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## Psychological interventions for coronary heart disease

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## **Psychological interventions for coronary heart disease (Review)**

Richards SH, Anderson L, Jenkinson CE, Whalley B, Rees K, Davies P, Bennett P, Liu Z, West R, Thompson DR, Taylor RS

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Psychological interventions for coronary heart disease.

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# Psychological interventions for coronary heart disease

Suzanne H Richards<sup>1,2</sup>, Lindsey Anderson<sup>3</sup>, Caroline E Jenkinson<sup>2</sup>, Ben Whalley<sup>4</sup>, Karen Rees<sup>5</sup>, Philippa Davies<sup>6</sup>, Paul Bennett<sup>7</sup>, Zulian Liu<sup>8</sup>, Robert West<sup>9</sup>, David R Thompson<sup>10</sup>, Rod S Taylor<sup>3</sup>

<sup>1</sup>Leeds Institute of Health Sciences, University of Leeds, Leeds, UK. <sup>2</sup>Primary Care, University of Exeter Medical School, Exeter, UK. <sup>3</sup>Institute of Health Research, University of Exeter Medical School, Exeter, UK. <sup>4</sup>School of Psychology, University of Plymouth, Plymouth, UK. <sup>5</sup>Division of Health Sciences, Warwick Medical School, University of Warwick, Coventry, UK. <sup>6</sup>School of Social and Community Medicine, University of Bristol, Bristol, UK. <sup>7</sup>Department of Psychology, University of Swansea, Swansea, UK. <sup>8</sup>Institute of Applied Health Research, College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK. <sup>9</sup>Wales Heart Research Institute, Cardiff University, Cardiff, UK. <sup>10</sup>Department of Psychiatry, University of Melbourne, Melbourne, Australia

Contact address: Rod S Taylor, Institute of Health Research, University of Exeter Medical School, Veysey Building, Salmon Pool Lane, Exeter, EX2 4SG, UK. [r.taylor@exeter.ac.uk](mailto:r.taylor@exeter.ac.uk).

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## ABSTRACT

### Background

Coronary heart disease (CHD) is the most common cause of death globally, although mortality rates are falling. Psychological symptoms are prevalent for people with CHD, and many psychological treatments are offered following cardiac events or procedures with the aim of improving health and outcomes. This is an update of a Cochrane systematic review previously published in 2011.

### Objectives

To assess the effectiveness of psychological interventions (alone or with cardiac rehabilitation) compared with usual care (including cardiac rehabilitation where available) for people with CHD on total mortality and cardiac mortality; cardiac morbidity; and participant-reported psychological outcomes of levels of depression, anxiety, and stress; and to explore potential study-level predictors of the effectiveness of psychological interventions in this population.

### Search methods

We updated the previous Cochrane Review searches by searching the following databases on 27 April 2016: CENTRAL in the Cochrane Library, MEDLINE (Ovid), Embase (Ovid), PsycINFO (Ovid), and CINAHL (EBSCO).

### Selection criteria

We included randomised controlled trials (RCTs) of psychological interventions compared to usual care, administered by trained staff, and delivered to adults with a specific diagnosis of CHD. We selected only studies estimating the independent effect of the psychological component, and with a minimum follow-up of six months. The study population comprised of adults after: a myocardial infarction (MI), a revascularisation procedure (coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)), and adults with angina or angiographically defined coronary artery disease (CAD). RCTs had to report at least one of the following outcomes: mortality (total- or cardiac-related); cardiac morbidity (MI, revascularisation procedures); or participant-reported levels of depression, anxiety, or stress.

## Data collection and analysis

Two review authors independently screened titles and abstracts of all references for eligibility. A lead review author extracted study data, which a second review author checked. We contacted study authors to obtain missing information.

## Main results

This review included 35 studies which randomised 10,703 people with CHD (14 trials and 2577 participants added to this update). The population included mainly men (median 77.0%) and people post-MI (mean 65.7%) or after undergoing a revascularisation procedure (mean 27.4%). The mean age of participants within trials ranged from 53 to 67 years. Overall trial reporting was poor, with around a half omitting descriptions of randomisation sequence generation, allocation concealment procedures, or the blinding of outcome assessments. The length of follow-up ranged from six months to 10.7 years (median 12 months). Most studies (23/35) evaluated multifactorial interventions, which included therapies with multiple therapeutic components. Ten studies examined psychological interventions targeted at people with a confirmed psychopathology at baseline and two trials recruited people with a psychopathology or another selecting criterion (or both). Of the remaining 23 trials, nine studies recruited unselected participants from cardiac populations reporting some level of psychopathology (3.8% to 53% with depressive symptoms, 32% to 53% with anxiety), 10 studies did not report these characteristics, and only three studies excluded people with psychopathology.

Moderate quality evidence showed no risk reduction for total mortality (risk ratio (RR) 0.90, 95% confidence interval (CI) 0.77 to 1.05; participants = 7776; studies = 23) or revascularisation procedures (RR 0.94, 95% CI 0.81 to 1.11) with psychological therapies compared to usual care. Low quality evidence found no risk reduction for non-fatal MI (RR 0.82, 95% CI 0.64 to 1.05), although there was a 21% reduction in cardiac mortality (RR 0.79, 95% CI 0.63 to 0.98). There was also low or very low quality evidence that psychological interventions improved participant-reported levels of depressive symptoms (standardised mean difference (SMD) -0.27, 95% CI -0.39 to -0.15; GRADE = low), anxiety (SMD -0.24, 95% CI -0.38 to -0.09; GRADE = low), and stress (SMD -0.56, 95% CI -0.88 to -0.24; GRADE = very low).

There was substantial statistical heterogeneity for all psychological outcomes but not clinical outcomes, and there was evidence of small-study bias for one clinical outcome (cardiac mortality: Egger test  $P = 0.04$ ) and one psychological outcome (anxiety: Egger test  $P = 0.012$ ). Meta-regression exploring a limited number of intervention characteristics found no significant predictors of intervention effects for total mortality and cardiac mortality. For depression, psychological interventions combined with adjunct pharmacology (where deemed appropriate) for an underlying psychological disorder appeared to be more effective than interventions that did not ( $\beta = -0.51$ ,  $P = 0.003$ ). For anxiety, interventions recruiting participants with an underlying psychological disorder appeared more effective than those delivered to unselected populations ( $\beta = -0.28$ ,  $P = 0.03$ ).

## Authors' conclusions

This updated Cochrane Review found that for people with CHD, there was no evidence that psychological treatments had an effect on total mortality, the risk of revascularisation procedures, or on the rate of non-fatal MI, although the rate of cardiac mortality was reduced and psychological symptoms (depression, anxiety, or stress) were alleviated; however, the GRADE assessments suggest considerable uncertainty surrounding these effects. Considerable uncertainty also remains regarding the people who would benefit most from treatment (i.e. people with or without psychological disorders at baseline) and the specific components of successful interventions. Future large-scale trials testing the effectiveness of psychological therapies are required due to the uncertainty within the evidence. Future trials would benefit from testing the impact of specific (rather than multifactorial) psychological interventions for participants with CHD, and testing the targeting of interventions on different populations (i.e. people with CHD, with or without psychopathologies).

## PLAIN LANGUAGE SUMMARY

### Psychological treatments for coronary heart disease

We reviewed the evidence to assess the effects of adding psychological treatments (talking therapies) to usual care for people with coronary heart disease (CHD; narrowing of the arteries supplying the heart) compared with people receiving usual care. We extracted results on the rates of death (any cause or cardiac-related); heart attacks; the need for revascularisation surgery (operation to restore the blood flow around the heart); and levels of depression, anxiety, and stress.

### Background

Heart attacks and cardiac (heart) surgery may be frightening and traumatic, and may lead some people to experience psychological problems. Some psychological characteristics are linked to the development and progression of cardiac complaints. Psychological treatments for depression, anxiety or stress are sometimes offered, either alone or as part of a rehabilitation programme. We tested whether there are any benefits from providing psychological therapies in addition to usual care for people with CHD. We only selected studies that followed people for at least six months.

### **Searches**

This is the third update of this review (previous versions 2004 and 2011). The evidence reported is current to April 2016.

### **Study characteristics**

We included 35 randomised controlled trials (clinical studies where people are randomly put into one of two or more treatment groups) with 10,703 participants. Most participants were men (77%), and had recently had a heart attack or undergone a surgical revascularisation procedure. Studies followed up participants for between six months and 10.7 years, with 12 months being the most common period. At baseline (start of the trial), 10 trials only recruited participants with CHD and an established psychological condition (mostly depression), 11 trials recruited people with varying levels of psychopathology, three studies excluded people with psychological conditions, and 11 studies did not report psychological status.

### **Study funding**

Thirteen studies did not report funding sources. Seven studies were funded by government grants, six through charitable foundations, and six through a mix of government and charitable funding. Two studies reported receiving some funding from private companies in addition to funds secured from government and charitable sources, and one study was university funded.

### **Key results**





Psychological interventions did not reduce mortality (any cause), or the risk cardiac surgery or having another heart attack. Psychological interventions reduced the risk of cardiac deaths and reduced participant-reported symptoms of depression, anxiety, and stress.

### **Quality of the evidence**

There is considerable uncertainty regarding the effects observed, as the quality of the evidence was either low (for cardiac mortality, non-fatal heart attack, depression, anxiety) or very low (for stress) for most measures, except deaths (any cause) or cardiac surgery, both of which had moderate quality of evidence.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Psychological intervention with or without other rehabilitation compared to control (usual care/other rehabilitation) for coronary heart disease (third update)						
<b>Patient or population:</b> people with coronary heart disease (third update) <b>Settings:</b> centre or home based (± telephone support) <b>Intervention:</b> psychological intervention ± other rehabilitation <b>Comparison:</b> control (usual care/other rehabilitation)						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control (usual care/other rehabilitation)	Psychological intervention +/- other rehabilitation				
<b>Total mortality</b> Deaths Follow-up: median 13 months	Study population		<b>RR 0.90</b> (0.77 to 1.05)	7776 (23 studies)	⊕⊕⊕○ <b>Moderate</b> <sup>1</sup>	-
	<b>91 per 1000</b>	<b>82 per 1000</b> (70 to 95)				
	Moderate population					
	<b>36 per 1000</b>	<b>32 per 1000</b> (28 to 38)				
<b>Cardiac mortality</b> Deaths Follow-up: median 57 months	Study population		<b>RR 0.79</b> (0.63 to 0.98)	4792 (11 studies)	⊕⊕○○ <b>Low</b> <sup>1,2</sup>	-
	<b>72 per 1000</b>	<b>57 per 1000</b> (45 to 71)				
	Moderate population					
	<b>49 per 1000</b>	<b>39 per 1000</b> (31 to 48)				

<b>Non-fatal MI</b> Follow-up: median 30 months	<b>Study population</b>		<b>RR 0.82</b> (0.64 to 1.05)	7845 (13 studies)	 <b>Low</b> <sup>1,3</sup>	-
	<b>95 per 1000</b>	<b>78 per 1000</b> (61 to 100)				
	<b>Moderate population</b>					
	<b>67 per 1000</b>	<b>55 per 1000</b> (43 to 70)				
<b>Revascularisation (CABG and PCI combined)</b> Follow-up: median 12 months	<b>Study population</b>		<b>RR 0.94</b> (0.81 to 1.11)	6822 (13 studies)	 <b>Moderate</b> <sup>1</sup>	-
	<b>121 per 1000</b>	<b>114 per 1000</b> (98 to 135)				
	<b>Moderate population</b>					
	<b>115 per 1000</b>	<b>108 per 1000</b> (93 to 128)				
<b>Anxiety</b> Follow-up: median 12 months	-	The mean anxiety in the intervention groups was <b>0.24 standard deviations lower</b> (0.38 to 0.09 lower)	-	3165 (12 studies)	 <b>Low</b> <sup>1,2</sup>	-
<b>Depression</b> Follow-up: median 12 months	-	The mean depression in the intervention groups was <b>0.27 standard deviations lower</b> (0.39 to 0.15 lower)	-	5829 (19 studies)	 <b>Low</b> <sup>1,4</sup>	-



<b>Stress</b> Follow-up: median 12 months	-	The mean stress in the intervention groups was <b>0.56 lower</b> (0.88 to 0.24 lower)	-	1255 (8 studies)	⊕○○○ <b>Very low</b> <sup>1,4,5</sup>	-
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\*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

**CABG:** coronary artery bypass graft; **CI:** confidence interval; **MI:** myocardial infarction; **PCI:** percutaneous coronary intervention; **RR:** risk ratio.

#### GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

<sup>1</sup> Random sequence generation, allocation concealment, or blinding of outcome assessors were poorly described in 50% or more of included studies.

<sup>2</sup> Egger test suggest evidence of asymmetry and therefore publication bias.

<sup>3</sup> The 95% CIs included both no effect and appreciable benefit or harm (i.e. CI < 0.75 or > 1.25).

<sup>4</sup> Moderate heterogeneity ( $I^2 > 50\%$ ).

<sup>5</sup> 95% CIs around the standardised mean difference did not include the value of a +0.5 at either the lower or upper limits, which is an indicator of clinical significance.

## BACKGROUND

### Description of the condition

Coronary heart disease (CHD) is the single leading cause of death globally, with ischaemic heart disease accounting for 7.4 million deaths in 2012 (WHO 2014), equivalent to approximately one-third of all deaths. In the UK, more than 1 in 7 men and nearly 1 in 10 women die from CHD (nearly 70,000 deaths each year), with most deaths caused by myocardial infarction (MI) (BHF 2016). However, the mortality rate from CHD is falling in the UK, largely through the introduction of evidence-based treatments and reductions in major risk factors (mostly smoking). The success achieved in reducing mortality means that many more people are living with CHD and may need support to manage their symptoms and prognosis. In the UK, it is estimated that 2.3 million people are living with CHD, over 60% of whom are male (BHF 2016). Cardiac events or cardiac surgery can be significant and distressing life events, and mental health comorbidity is prevalent for people living with CHD (Tully 2014). Psychopathologies, such as anxiety and depression, also constitute an independent risk factor for cardiac morbidity and mortality (Gale 2014; Lichtman 2014). As a consequence, the need to address stress, psychosocial factors (including lack of social support), and other psychopathologies (mood disorders such as depression, anxiety) are recognised within conventional cardiac care (Lespérance 2000).

### Description of the intervention

Many definitions of cardiac rehabilitation (CR) have been proposed. The following definition encompasses the key concepts of CR: “The coordinated sum of activities required to influence favourably the underlying cause of cardiovascular disease, as well as to provide the best possible physical, mental and social conditions, so that the patients may, by their own efforts, preserve or resume optimal functioning in their community and through improved health behaviour, slow or reverse progression of disease” (BACPR 2014). CR is offered to people after cardiac events to aid recovery and prevent further cardiac illness (Lespérance 2000). As part of their secondary rehabilitation, people may be offered interventions which specifically aim to influence psychological or psychosocial outcomes (BACPR 2014; Piepoli 2014). These psychological or psychosocial interventions are varied and may range from organisational efforts to improve patient communication and support, to empirically supported, psychotherapies used to target diagnosed psychopathology in people with cardiac conditions. Furthermore, psychological or psychosocial interventions may incorporate other elements of CR such as the modification of cardiovascular risk factors (e.g. diet and lifestyle advice, or exercise); in some cases, the intervention may be described as ‘psychological’ only to the extent that psychological techniques are used to further other treatment goals through promoting behavioural change. In this review,

we aimed to assess the effectiveness of psychological interventions compared with usual care on outcomes relating to clinical events and psychological outcomes, and to explore potential study-level predictors of the effectiveness of psychological interventions in people with CHD.

### Previous Cochrane Reviews

The original Cochrane Review of psychological interventions for CHD was undertaken by Rees 2004, and was subsequently updated by Whalley 2011. The 2011 update reported a marked variation in the nature of interventions across studies, and in relation reported substantial statistical heterogeneity in effects for a number of outcomes. Meta-analysis of all studies showed no strong evidence that psychological interventions had an effect on total deaths, risk of revascularisation, or non-fatal MI, although a smaller group of studies reported a positive effect of psychological interventions on cardiac mortality (5 trials, 3893 participants; risk ratio (RR) 0.80, 95% confidence interval (CI) 0.64 to 1.00). While there was insufficient evidence to pool data on participant stress levels, there was evidence that psychological interventions improved depressive symptoms (12 trials, 5041 participants; standardised mean difference (SMD) -0.21, 95% CI -0.48 to -0.08) and anxiety (8 trials, 2771 participants; SMD -0.25, 95% CI -0.48 to -0.03), although the resultant estimates lacked precision.

### Changes in this update review

Starting with the inclusion criteria proposed by Whalley 2011, this third update excluded studies where the majority of the participant sample (50% or more) had other cardiac conditions, such as heart failure or atrial fibrillation, or were implanted with either cardiac resynchronisation therapy (CRT) or implantable cardioverter defibrillators (ICD). This restriction was introduced as, since the mid-2000s, CR services have taken an increasingly diverse case-mix, and hence the trials on which they are based are recruiting participants of very different baseline risk profiles. At the same time, there has been substantial interest and trial activity around assessing psychological interventions for people with specific groups of comorbidities (e.g. participants with depression and at least one long-term condition such as CHD or diabetes). In trials exploring the effectiveness of psychological interventions targeting comorbid populations, we have only included (otherwise eligible) trials if the outcome data for participants with CHD were reported separately from those with other long-term conditions. Finally, this update included an assessment of the quality of the evidence for reported outcomes using the GRADE framework (Schünemann 2011).

### How the intervention might work

There is considerable evidence that negative emotional states, such as anxiety (Tully 2014) and depression (Dickens 2013), are related to poor cardiac outcomes, although there remains uncertainty in the theoretical and empirical literature on the causal mechanisms linking mood disorders and worse clinical outcomes, and of which subgroups of individuals may be at particularly high risk of poor outcomes and who might be targeted by novel interventions (Dickens 2015; Tully 2014). Research has also shown that long-term stress can predict both the onset of CHD, as well as the risk of recurrent CHD events and mortality in people with existing CHD (Stephoe 2012). The causal pathways between the well-established physiological reaction to psychological stress, involving the hypothalamic-pituitary-adrenocortical and sympatho-adrenomedullary axes, and CHD disease progression is not well understood (Stephoe 2012). Given this, many psychological interventions used within the context of CR include treatment targets such as alleviating low mood, or reducing long-term stress. It is plausible that no single causal mechanism is likely to explain the complex relationship between CHD, mood, and stress fully, and how this might also influence wider factors such as patient engagement with other components of CR, such as adherence to exercise and medication, and other components of cardiac risk factor reduction (Dickens 2015; Steptoe 2012).

### Why it is important to do this review

The previous update by Whalley 2011 reported on pooled analysis across a range of clinical and psychological outcomes, but noted that there was considerable uncertainty in their findings as the samples available for analysis were small, limiting the precision of the effect estimates and hence confidence in the interpretation of results. Since 2011, there has been increasing interest and research activity in the area, with a number of high-profile randomised controlled trials (RCTs) publishing results for the first time. Thus, by updating this review, and adding a number of new trials into pooled analyses, our intention was to revisit earlier analyses, and yield new estimates of pooled treatment effects of psychological interventions with greater precision. We also sought to extract new data on the cost-effectiveness of psychological interventions to complement clinical outcomes.

## OBJECTIVES

To assess the effectiveness of psychological interventions (alone or with cardiac rehabilitation) compared with usual care (including cardiac rehabilitation where available) for people with CHD on total mortality and cardiac mortality, cardiac morbidity, and the participant-reported psychological outcomes of levels of depression, anxiety, and stress; and to explore potential study-level predictors of the effectiveness of psychological interventions in this population.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

RCTs with parallel group design comparing the independent effects of a psychological intervention versus a usual care comparator. Eligible studies could include psychological interventions delivered alongside CR services, as long as this was routinely offered as part of usual care.

#### Types of participants

Adults of all ages with CHD, with or without clinical psychopathology, managed in either hospital or community settings. Participants included people who had experienced an MI, a revascularisation procedure (coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI)), and people with angina, or angiographically defined CHD. We excluded studies where the majority of the participant sample (50% or more) had other cardiac conditions, such as heart failure or atrial fibrillation, or were implanted with CRT or ICD.

#### Types of interventions

We considered all psychological interventions delivered by health-care workers with specific training in psychological techniques. Criteria for specific training were liberal (i.e. included even very short periods of training), but excluded interventions delivered by social workers or cardiac nursing staff unless specific mention was made of training in delivering psychological interventions. In addition, we excluded studies where they evaluated interventions based on psychological principles (e.g. social learning theory, motivational interviewing) which were solely directed at improving adherence to other efficacious treatments (e.g. cardiac medications, exercise) or the modification of cardiac risk factors (e.g. smoking, diet).

Trials were only considered where the effect of the psychological intervention could be evaluated independently. Thus, we included studies that compared psychological treatment with usual care. Usual care may have included the routine medical care provided to people with CHD, and cointerventions including referral to or participation in (or both) a comprehensive CR programme. Although psychological interventions often include cointerventions (e.g. cardiac risk factor education), we excluded studies where the cointerventions were not offered in the usual care. We included studies where psychopharmacological interventions were solely or disproportionately available to the treatment group (e.g. Black 1998; Davidson 2010; ENRICHD Investigators 2000) as psychological treatments may be offered in conjunction with psychopharmacological treatments, and may be more effective in combina-

tion than alone (Butler 2006). More recent studies are also seeking to test psychological interventions in comorbid populations (i.e. people with depression, and either acute coronary syndrome (ACS) or diabetes). These interventions were eligible for inclusion as long as the outcome data were reported separately and could be extracted for the subgroup of people with heart disease. Finally, we considered trials where the follow-up was six months or more following the start of the intervention.

### Classification of interventions

The first version of this Cochrane Review classified trials according to whether they reported using 'stress management procedures' (Rees 2004). Stress management was defined as the use of specific cognitive behavioural strategies used to help the patient reduce, or manage, their stress. These included learning relaxation techniques, the use of cognitive techniques such as self-instruction training (Meichenbaum 1985) and cognitive challenge (e.g. Beck 1997), with or without consideration of specific coping strategies to be used at times of stress. Less specific approaches, such as therapeutic counselling that did not concentrate on behaviour change, cognitive challenge/restructuring (Allison 2000), or educational interventions such as Frasure-Smith 1985, were excluded from this definition. Also excluded were self-management techniques used to change cardiac risk factors such as smoking and low levels of exercise. Study eligibility was expanded by Whalley 2011, and this third update used expanded eligibility criteria, to include psychological treatments targeting mood states (e.g. depression, anxiety) in addition to stress management strategies. Whalley 2011 also developed a taxonomy of psychological interventions to aid interpretation of the data, extracting information on the treatment aims of each intervention (e.g. provision of risk information, treatment of psychopathology such as depression or anxiety), and the components of the treatment (e.g. providing standardised health information, relaxation techniques, cognitive challenge). See the [Data collection and analysis](#) section for details.

### Extraction of additional study characteristics

We extracted information on other study characteristics for all trials identified in this update, as well as those carried forward from the previous reviews. Variables included the proportion of men, ethnicity, mean sample age, and whether the sample included participants with symptoms indicative of a psychopathology. We extracted new information on study design for all eligible papers including: dates of participant recruitment; follow-up schedule and the maximum duration of follow-up; eligibility criteria; baseline CHD and psychopathology indications (with proportions); participant ethnicity; and a fuller description of the interventions compared. Unlike Whalley 2011 (but consistent with Rees 2004), we restricted analysis to outcomes extracted at the final follow-up, irrespective of whether data were available for multiple time points six months or more after randomisation.

### Types of outcome measures

We selected papers which reported at least one of the primary outcomes listed below.

#### Primary outcomes

- Total mortality (all cause) and cardiac mortality.
- Cardiac morbidity: non-fatal MI, revascularisation (CABG, PCI).
- Participant-reported symptoms of anxiety, depression, and stress.

#### Secondary outcomes

- Health-related quality of life (HRQoL).
- Other psychological outcomes (e.g. vital exhaustion, Type A behaviours, hostility, psychological distress).
- Return to work.
- Cost-effectiveness data.

### Search methods for identification of studies

#### Electronic searches

The search from the previously published Cochrane Review (Whalley 2011) was updated in January 2015 and 27 April 2016. We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library (2016, Issue 3), MEDLINE (Ovid) (1946 to April week 2 2016), Embase (Ovid, 1980 to week 17 2016), PsycINFO (Ovid, 1806 to April week 3 2016), and CINAHL (EBSCO, 1937 to 27 April 2016). We searched the [WHO International Clinical Trials Registry Platform](#) and the [US ClinicalTrials.gov](#) registry on 18 June 2016 for ongoing clinical trials.

We designed search strategies with reference to those of the previous systematic review (Whalley 2011). We added new search terms to expand the search to include PCI and related interventions, and angina-related conditions such as ACS. We also added terms relating to education and psychological interventions to better reflect the comprehensive nature of CR. We searched the databases using subject headings and free-text terms and applied filters to limit the search to RCTs. The RCT filter for MEDLINE was the Cochrane sensitivity-maximising RCT filter, and for Embase, we applied terms recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011). We adapted this filter to all other databases except CENTRAL. We applied date limits to retrieve only newly added studies since the last update; however, when we added new terms to the strategies, we searched them without date limits. There were no language limitations, and we considered variations in terms used and spellings of terms in different countries so that the search strategy did not miss studies

because of such variations. See Appendix 3 for details of the search strategies used.

### Searching other resources

We handsearched reference lists of retrieved articles and systematic reviews published since the last update, for any studies not identified by the electronic searches.

### Data collection and analysis

The methods adopted in this third update are described below.

### Selection of studies

Two review authors (CJ and either SR or LA) independently examined the titles and abstracts of the citations identified from the searches, and retrieved full copies of potentially relevant references. We independently reviewed these references for inclusion. We resolved disagreements about study inclusions with consensus among the review authors, or referral to an independent adjudicator who had coauthored in the second update (BW or RT). We reconsidered studies included in the previous reviews for inclusion based on the slightly narrower inclusion criteria adopted for this update review following the same procedures.

### Data extraction and management

After studies identified by the updated searches or from previous versions had been formally included in the review, one review author (CJ or LA) extracted data onto a data collection form which had been piloted on two RCTs included in the review, and one review author (SR) cross-checked entries. For studies identified in the April 2016 search, two review authors (SR and LA) independently extracted outcome data to be consistent with the MECIR guidance (Chandler 2013). We resolved disagreements through discussion. One review author (CJ) extracted additional information from studies included in previous reviews, and reported for the first time in this update, and one review author (SR) cross-checked information. If data were presented numerically (in tables or text) and graphically (in figures), we used the numeric data because of possible measurement error when estimating from graphs.

### Descriptive information on study design and interventions

We extracted data on participant characteristics (e.g. age, sex, ethnicity, CHD diagnosis, whether psychopathology was present at baseline) and details of the interventions. We noted descriptive data on settings, the clinicians delivering the psychological interventions, the mode (group, individual, or mixed), duration, and frequency of sessions. As the psychological interventions were frequently multifactorial, we extracted the core treatment goals and

techniques used by psychological interventions (based on the taxonomy developed by Whalley 2011). First, we identified treatment goals of psychological therapy, and whether treatment(s) targeted a specific psychological disorder (depression, anxiety, Type A behaviours including anger or hostility, exhaustion, stress), as opposed to a combination of disorders or states. We recorded the components used to achieve the stated treatment goal(s) including: self-awareness or self-monitoring techniques, relaxation techniques, cognitive challenge or restructuring techniques, and client-led discussion or emotional support. We noted cointerventions provided alongside the psychological therapy (e.g. CHD risk education, behavioural techniques targeting CHD risk factors, or pharmacological management), and documented the content of usual care. We extracted the scheduling of follow-up data collection and information on outcomes of interest to this review.

If there were multiple reports of the same study, we assessed the related publications for additional data. We extracted outcome results for the final follow-up assessed. We contacted study authors where necessary to provide additional information.

### Assessment of risk of bias in included studies

For all studies, including those in the previous reviews, we conducted standard risk of bias assessments using the Cochrane 'Risk of bias' assessment tool (Higgins 2011). Due to the nature of the interventions studied, assessing the blinding of treatment assignment was not deemed possible; instead, we reported on the blinding of outcome assessments. We also assessed three further risk of bias criteria: whether the study groups were balanced at baseline; if the study groups received comparable care (apart from the psychological component of the intervention); and whether an intention-to-treat analysis was undertaken. The criteria used for assessing these last three risk of bias domains were as follows.

#### Groups balanced at baseline

- Low risk of bias: the characteristics of the participants in the intervention and control groups at baseline were reported to be comparable or could be judged to be comparable (e.g. baseline data reported in Table 1) in terms of likely main prognostic factors.
- Unclear risk of bias: it was not reported whether the participants' characteristics in the two groups were balanced at baseline and there was inadequate information reported (e.g. no Table 1) to assess this.
- High risk of bias: there was evidence of substantive imbalance in the baseline characteristics of the intervention and control groups with regard to likely major prognostic factors.

#### Intention-to-treat analysis

- Low risk of bias: the trial reported that the analyses were conducted according to an intention-to-treat analysis, and

included all the principles of such an analysis (e.g. keeping participants in the intervention groups to which they were randomised, regardless of the intervention they actually received and measures outcome data on all or the majority of participants (i.e. greater than 80% of those randomised) or includes imputation of all missing data in the analysis, using appropriate methodology (e.g. multiple imputation)).

- Unclear risk of bias: it was unclear if the trial had performed an intention-to-treat analysis.
- High risk of bias: the trial did not include an intention-to-treat analysis, or there was a substantive loss of outcome data (e.g. greater than 20%) and analyses were performed according to imputation methods known to create bias such as last observation carried forward.

#### **Groups received comparable treatment (except psychological intervention)**

- Low risk of bias: all cointerventions were delivered equally across intervention and control groups.
- Unclear risk of bias: there was insufficient information to access whether cointerventions were equally delivered across groups.
- High risk of bias: the cointerventions were not delivered equally across intervention and control groups.

One review author (CJ or LA) made risk of bias assessments, and one review author (SR) checked assessments. We resolved any discrepancies by discussion. Details of the assessments of risk of bias for each included trial are shown in the [Characteristics of included studies](#) table.

#### **Measures of treatment effect**

We extracted primary outcomes relating to clinical event data as dichotomous outcomes for each study. We expressed event data as RR with associated 95% CI, and study sample sizes based on the number randomised to treatment conditions.

We extracted primary psychological outcomes (depression, anxiety, and stress) as continuous variables, and expressed them as the mean change from baseline to follow-up, using the standard deviation (SD) difference from baseline to follow-up, for each comparison group (sample sizes based on number of participants completing assessments at each time point). If the mean change from baseline to follow-up was not reported, we entered the group mean and SD at the follow-up. In some cases, the SD was calculated using standard formulae from a standard error ([Freedland 2009](#); [Schneider 2012](#)), 95% CIs ([Davidson 2010](#)), or a range ([Roncella 2013](#); estimated applying range/4). One study reported two outcomes for depression ([Freedland 2009](#)). Here, we classified primary outcome data as the measure identified as such by the study authors and then entered it into the meta-analysis; the other depression measure was reported under 'other psychological

outcomes'. Where SDs for differences had not been reported in the source papers, we allowed for within-participant correlation from baseline to follow-up measurements by using an assumed correlation ([Follmann 1992](#)). For a base-case analysis, we assumed a correlation of 0.7 for both depression and anxiety measures.

#### **Unit of analysis issues**

In accordance with Section 9.3.1 of the *Cochrane Handbook for Systematic Reviews of Intervention* ([Higgins 2011](#)), we ensured that the analysis was appropriate to the level at which randomisation occurred. All studies included in this review were simple parallel-group RCTs, and so there were no issues relating to unit of analysis.

#### **Dealing with missing data**

We contacted investigators to verify or to obtain missing numerical outcome data where possible (e.g. when data on the SD of a mean change was omitted). If the missing data were thought to introduce serious bias, we planned to explore the impact of including such studies on the overall assessment of results by a sensitivity analysis.

#### **Assessment of heterogeneity**

We explored heterogeneity among included studies qualitatively (by comparing the characteristics of included studies) and quantitatively (using the  $\chi^2$  test of heterogeneity and  $I^2$  statistic).

#### **Assessment of reporting biases**

We investigated the possibility of small-study bias for each of the outcomes included in meta-analyses visually (using funnel plots) and statistically for primary outcomes ([Egger 1997](#)).

#### **Data synthesis**

For dichotomous outcomes (relating to clinical events), we used RR with 95% CI. For continuous data (relating to psychological outcomes), we used mean difference (MD) with 95% CI, or, where an outcome was measured and reported in more than one way, a standardised mean difference (SMD) with 95% CIs. A priori, we elected to pool data using random-effects models due to the substantial clinical heterogeneity in treatments identified. Compared with a fixed-effect model, the random-effects model provides a more conservative statistical comparison of the difference between intervention and control by typically providing a wider CI around the effect estimate. For clinical events data, where there was no evidence of heterogeneity ( $I^2$  statistic) observed in any of the random-effects models, if a statistically significant difference was observed using a random-effects model, we also report the fixed-effect pooled estimate and 95% CI. We did this because of the tendency of smaller trials, which are more susceptible to publication bias, to be overweighted with a random-effects analysis.



For secondary outcomes, where there were insufficient data, or where it was inappropriate to combine studies statistically, we presented a narrative review using the vote counting method.

One review author (LA) used GRADEpro software to assess the quality of outcomes reported in the review based on the following factors (GRADEpro GDT 2015): indirectness of evidence, unexplained heterogeneity, publication bias, risk of bias due to study design limitations, and imprecision of results (Balslem 2011). A second review author (RT) checked the assessment.

### Subgroup analysis and investigation of heterogeneity

We undertook exploratory meta-regression to explore heterogeneity and examine potential treatment effect modifiers for a selection of outcomes and potential explanatory variables. We tested hypotheses that there may be differences in the effect of psychological interventions on total mortality, cardiac mortality, and depression and anxiety scores across particular subgroups:

- targeting of psychological interventions (non-selected CHD population (including not reported) versus CHD population with clinically established psychological disorder);
- mode of intervention (individual (including not reported), group, individual and group);
- family involved in intervention (no, yes);
- cardiac risk factor education as part of intervention (no, yes);
- psychological intervention also targeted behaviour change for cardiac risk factors (no, yes);
- treatment targets (depression (no, yes), anxiety (no, yes), stress management (no, yes), Type A behaviour (no, yes)); and
- treatment components (relaxation (no, yes), stress management techniques (no, yes), cognitive techniques (no, yes), emotional support or client-led discussion, or both (no, yes), adjunct pharmacology (no, yes)).

When information was not reported explicitly, or implied through intervention descriptions, we classified explanatory variables as 'no' for these studies. The explanatory variables were selected a priori following the approach outlined by Whalley 2011, although we restricted analyses to a smaller group of potential explanatory variables, electing not to test the impact of some variables (e.g. those relating to treatment dose or intensity) due to concerns over data quality. Given the relatively small ratio of trials to covariates, we limited meta-regression to univariate analysis (Deeks 2011). We conducted meta-regression analysis using the 'metareg' command in STATA (StataCorp 2013).

### Sensitivity analysis

Given that we pooled continuous outcomes across studies that reported either change or final value scores using the SMD methods, we undertook a sensitivity analysis to pool change and final value scores studies separately. As the direction of between-group difference was consistent between these two groups of studies, we reported the results for these outcomes pooled across all studies. We conducted a sensitivity analysis for the one study where the SDs around the group effects were estimated from range data, as this estimate may lead to a spuriously narrow 95% CI within the meta-analysis (Roncella 2013).

## RESULTS

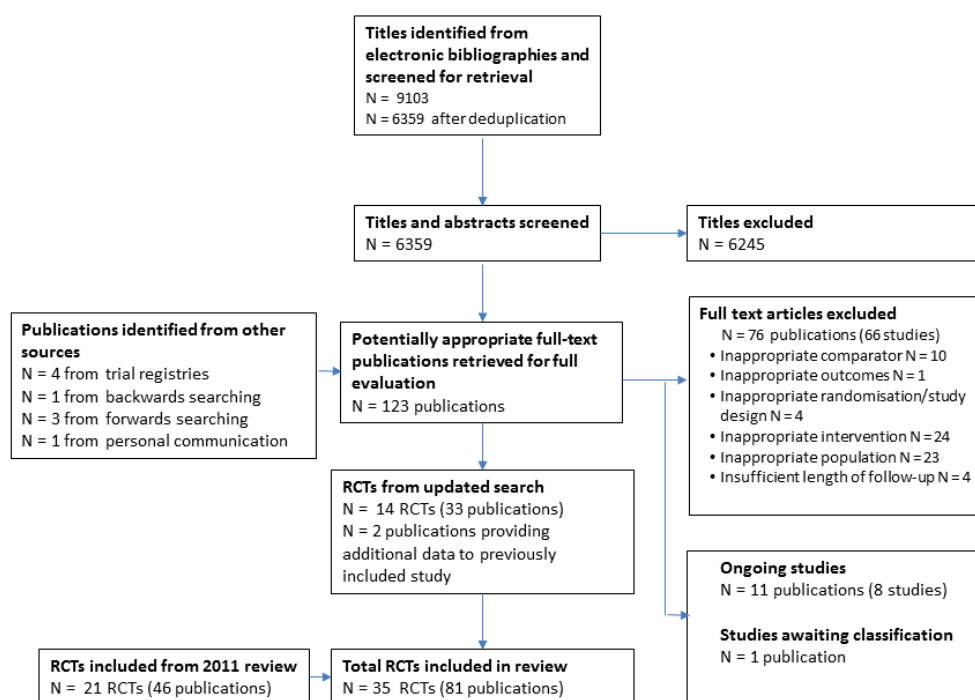
### Description of studies

The second update identified 24 studies that met the inclusion criteria. When reviewing these studies for inclusion in this third update, we subsequently excluded three studies: Cowan 2001 included an ineligible participant population; Hofman Bang 1999 had an inappropriate control group; and Ibrahim 1974 had not used a randomised design. Thus 21 studies were brought forward into this updated review. At this update, Peng 2005 was fully translated from Chinese into English, and, while still eligible as it reported data on a composite measure of clinical outcomes at one-year follow-up, the data for the psychological outcomes of anxiety and depression were no longer eligible as both were collected at a four-week, post-treatment follow-up only and thus we removed the anxiety and depression data from the meta-analyses.

### Results of the search

In addition to the 21 studies brought forward from the 2009 update, searches between 2009 and 2016 yielded 6359 titles and abstracts (Figure 1), from which 115 papers were selected for review. Of these, 12 studies (29 publications) met the inclusion criteria (Davidson 2010; Freedland 2009; Gulliksson 2011; Merswolken 2011; Neves 2009; O'Neil 2015; Oranta 2010; Rakowska 2015; Roncella 2013; Schneider 2012; Turner 2013; Turner 2014), while one additional study (two publications) was identified through backwards citation searching (Lie 2007), and one study was identified through personal communication with experts in the field (Blumenthal 2016). Two additional papers provided new data for trials (Blom 2009 for Koertge 2008; Saab 2009 for ENRICH Investigators 2000) already included in the second update.

**Figure 1. Flow diagram summarising study selection. N: number of RCT: randomised controlled trial**



## Included studies

The review included 35 studies (81 publications) reporting data from 10,703 participants. Twelve studies were conducted in the USA (Black 1998; Blumenthal 2016; Brown 1993; Burgess 1987; Davidson 2010; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; McLaughlin 2005; Rahe 1979; Schneider 2012; Stern 1983), 11 in Scandinavian countries (Appels 2005; Burell 1996a; Claesson 2005; Elderen-van-Kemenade 1994; Gulliksson 2011; Koertge 2008; Lie 2007; Merswolken 2011; Oranta 2010; Sebrechts 2005; Van-Dixhoorn 1999), four in Australia (O'Neil 2015; Oldenburg 1985; Turner 2013; Turner 2014), three in the UK (Gallacher 1997; Jones 1996; Mayou 2002), and the remainder conducted in other European nations (Michalsen 2005; Neves 2009; Rakowska 2015; Roncella 2013), and China (Peng 2005).

## Settings

In terms of settings, 13 studies did not report where the intervention was delivered (Burell 1996a; Claesson 2005; Davidson

2010; Friedman 1982; Gulliksson 2011; Merswolken 2011; Neves 2009; Peng 2005; Roncella 2013; Schneider 2012; Sebrechts 2005; Stern 1983; Van-Dixhoorn 1999). Nine studies reported interventions taking place in a hospital as either an inpatient, or other unspecified hospital location (Appels 2005; Brown 1993; Elderen-van-Kemenade 1994; Koertge 2008; Mayou 2002; O'Neil 2015; Oldenburg 1985; Rakowska 2015; Turner 2014). Seven studies reported taking place in a clinic setting, which could include a CR clinic, a hospital outpatient facility, or community clinic (Black 1998; Blumenthal 2016; Freedland 2009; Gallacher 1997; Jones 1996; Rahe 1979; Turner 2013). Four studies were described as being home-based, with or without telephone support (Burgess 1987; ENRICHD Investigators 2000; Lie 2007; McLaughlin 2005), with one of these studies also offering clinic appointments as needed (ENRICHD Investigators 2000). The remaining two studies offered a mixed intervention composed of an initial stay in a retreat followed by clinic appointments (Michalsen 2005) and a hospital setting with telephone support (Oranta 2010).



## Funding

Twelve studies did not report funding sources (Black 1998; Brown 1993; Burell 1996a; Elderen-van-Kemenade 1994; Gallacher 1997; Lie 2007; Merswolken 2011; Neves 2009; Oldenburg 1985; Oranta 2010; Roncella 2013; Van-Dixhoorn 1999), and this was not translated for one study (Peng 2005). Seven studies were funded by government research grants (Blumenthal 2016; Davidson 2010; Freedland 2009; O'Neil 2015; Rahe 1979; Schneider 2012; Stern 1983), six through charitable foundations (Burgess 1987; Mayou 2002; Michalsen 2005; Sebrechts 2005; Turner 2013; Turner 2014), and six through a mix of government and charitable funding (Appels 2005; Claesson 2005; Gulliksson 2011; Jones 1996; Koertge 2008; McLaughlin 2005). Two studies reported receiving an element of funding from private companies in addition to funds secured from government or charitable sources (or both) (ENRICHD Investigators 2000; Friedman 1982), and one study was university funded (Rakowska 2015).

## Conflicts of interest

Twenty-one studies did not report potential conflicts of interest (Appels 2005; Black 1998; Brown 1993; Burell 1996a; Burgess 1987; Claesson 2005; Davidson 2010; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gallacher 1997; Lie 2007; Mayou 2002; Neves 2009; Oldenburg 1985; Rahe 1979; Roncella 2013; Sebrechts 2005; Stern 1983; Van-Dixhoorn 1999), and were not translated for one study (Peng 2005). Eleven authorship teams explicitly declared no conflicts of interest (Blumenthal 2016; Gulliksson 2011; Jones 1996; Koertge 2008; McLaughlin 2005; Merswolken 2011; Michalsen 2005; Oranta 2010; Rakowska 2015; Turner 2013; Turner 2014), while the remaining two teams reported that one or more of the authors had a potential conflicts of interest (O'Neil 2015; Schneider 2012).

## Participants

The mean age of participants recruited by the 35 included studies ranged from 53 to 67 years (median 59.6 years). The proportion of men ranged from 0% to 100% (median 77.0%). A mean of 65.7% of participants had been referred to treatment because of an MI, and 27.4% of participants had undergone some form of revascularisation (e.g. CABG, PCI). Although we had anticipated more diverse cardiac populations being recruited into trials as a reflection of changing clinical practice in rehabilitation settings, only two trials that were deemed eligible had included participants with cardiac conditions other than ACS and angina (Peng 2005; Turner 2013). Thirty-six percent of Peng 2005's sample included participants with either arrhythmias or heart failure, while 12% of Turner 2013's sample included people with congestive heart failure, chronic atrial fibrillation, or other cardiomyopathies. Ten of the 35 studies only recruited participants with a psychopathology (Black 1998; Brown 1993; Davidson 2010;

Freedland 2009; McLaughlin 2005; Merswolken 2011; O'Neil 2015; Rakowska 2015; Turner 2013; Turner 2014), and two studies had inclusion criteria that included a psychopathology or another criterion, or both (ENRICHD Investigators 2000; Stern 1983). Of these, the majority of studies selected participants with confirmed depression; only two studies selected participants exhibiting psychological distress (Black 1998; Brown 1993); two studies recruited participants with anxiety with (Merswolken 2011) or without (McLaughlin 2005) comorbid depression; and one study selected participants with increased levels of perceived stress (Rakowska 2015). Although not an inclusion criterion, nine studies reported levels of depression as part of the baseline characteristics of study participants (Appels 2005; Blumenthal 2016; Jones 1996; Koertge 2008; Lie 2007; Michalsen 2005; Oranta 2010; Roncella 2013; Sebrechts 2005), with estimates ranging from 3.8% (Michalsen 2005) to 53% (Koertge 2008). Three studies reported anxiety levels from 32% (Jones 1996; Lie 2007) to 53% (McLaughlin 2005). Of the remaining studies, only three studies excluded people with established psychological conditions (Gallacher 1997; Mayou 2002; Van-Dixhoorn 1999), with the remaining 11 studies not reporting the inclusion of individuals with psychopathology or not measuring participant-reported psychological outcomes (or both) at baseline (Burell 1996a; Burgess 1987; Claesson 2005; Elderen-van-Kemenade 1994; Friedman 1982; Gulliksson 2011; Neves 2009; Oldenburg 1985; Peng 2005; Rahe 1979; Schneider 2012).

## Interventions

Thirty-one studies reported the amount of time participants spent in contact with interventionists (not reported by Burgess 1987; Elderen-van-Kemenade 1994; Friedman 1982; Turner 2014), but there was substantial variability in intensity of treatments offered. The number of hours spent in treatment across the different studies ranged from a mean of two to 96 hours (median 12 hours). The majority of the interventions were based on group therapy sessions (20 studies; Appels 2005; Blumenthal 2016; Brown 1993; Burell 1996a; Claesson 2005; Freedland 2009; Friedman 1982; Gallacher 1997; Gulliksson 2011; Koertge 2008; Merswolken 2011; Michalsen 2005; Neves 2009; Peng 2005; Rahe 1979; Sebrechts 2005; Stern 1983; Turner 2013; Turner 2014; Van-Dixhoorn 1999), and five studies comprised a mix of group and individual sessions (Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Jones 1996; Roncella 2013; Schneider 2012), with the remaining 10 trials delivering treatment on an individual basis only (Black 1998; Burgess 1987; Davidson 2010; Lie 2007; Mayou 2002; McLaughlin 2005; O'Neil 2015; Oldenburg 1985; Oranta 2010; Rakowska 2015). Eleven studies explicitly stated that participants' families were included in treatment (Appels 2005; Brown 1993; Burgess 1987; Elderen-van-Kemenade 1994; Jones 1996; Lie 2007; Mayou 2002; Oldenburg 1985; Rahe 1979; Roncella 2013; Sebrechts

2005), while the remainder did not report this information. Although the quality and detail of reporting was highly variable, the available information was used to categorise the treatment aims and components of psychological interventions. Twenty-three studies evaluated psychological interventions with more than one treatment aim, and thus included therapies with multiple components (Appels 2005; Black 1998; Blumenthal 2016; Burell 1996a; Burgess 1987; Claesson 2005; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gulliksson 2011; Jones 1996; Koertge 2008; Lie 2007; Mayou 2002; McLaughlin 2005; Merswolken 2011; O'Neil 2015; Oranta 2010; Peng 2005; Rakowska 2015; Sebrechts 2005; Stern 1983; Turner 2014). Common aims of treatments included:

- stress (22 studies: Appels 2005; Black 1998; Blumenthal 2016; Brown 1993; Claesson 2005; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gallacher 1997; Gulliksson 2011; Jones 1996; Koertge 2008; Merswolken 2011; Michalsen 2005; Neves 2009; Oldenburg 1985; Peng 2005; Rakowska 2015; Schneider 2012; Sebrechts 2005; Stern 1983; Van-Dixhoorn 1999);
- anxiety (16 studies: Appels 2005; Black 1998; Burell 1996a; Burgess 1987; Claesson 2005; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Jones 1996; Koertge 2008; Lie 2007; Mayou 2002; McLaughlin 2005; Merswolken 2011; O'Neil 2015; Peng 2005; Turner 2014);
- depression (17 studies: Black 1998; Burell 1996a; Burgess 1987; Claesson 2005; Davidson 2010; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Jones 1996; Koertge 2008; Lie 2007; Mayou 2002; McLaughlin 2005; O'Neil 2015; Oranta 2010; Peng 2005; Turner 2013; Turner 2014);
- Type A behaviour including anger and hostility (12 studies: Appels 2005; Black 1998; Blumenthal 2016; Burell 1996a; ENRICHD Investigators 2000; Friedman 1982; Gulliksson 2011; Koertge 2008; Oldenburg 1985; Sebrechts 2005; Stern 1983; Turner 2014);
- improved disease adjustment (11 studies: Burell 1996a; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gulliksson 2011; Jones 1996; Koertge 2008; Lie 2007; Mayou 2002; McLaughlin 2005); and
- reduced vital exhaustion (three studies: Appels 2005; ENRICHD Investigators 2000; Koertge 2008).

In addition, cointerventions were offered in many studies including:

- improving awareness of cardiac risk factors (16 studies: Burell 1996a; Claesson 2005; Elderen-van-Kemenade 1994; Friedman 1982; Gulliksson 2011; Jones 1996; Koertge 2008; Mayou 2002; Michalsen 2005; O'Neil 2015; Rahe 1979; Rakowska 2015; Roncella 2013; Sebrechts 2005; Stern 1983; Turner 2014);
- attempting to effect changes in behaviours related to cardiac risks such as reducing smoking or salt intake (19 studies: Appels 2005; Black 1998; Blumenthal 2016; Brown 1993; Burell

1996a; Claesson 2005; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Friedman 1982; Gallacher 1997; Mayou 2002; McLaughlin 2005; Michalsen 2005; O'Neil 2015; Peng 2005; Rakowska 2015; Roncella 2013; Sebrechts 2005; Stern 1983); and

- providing a pharmacological cointervention for the psychological disorder, where deemed clinically appropriate (three studies: Black 1998; Davidson 2010; Roncella 2013).

Common components of psychological treatments included:

- relaxation techniques (20 studies: Appels 2005; Black 1998; Blumenthal 2016; Brown 1993; Burell 1996a; Claesson 2005; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gallacher 1997; Jones 1996; Koertge 2008; Mayou 2002; Michalsen 2005; Neves 2009; Peng 2005; Roncella 2013; Sebrechts 2005; Stern 1983; Van-Dixhoorn 1999);
- self-awareness and self-monitoring (20 studies: Appels 2005; Blumenthal 2016; Burell 1996a; Claesson 2005; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gallacher 1997; Gulliksson 2011; Jones 1996; Koertge 2008; McLaughlin 2005; Michalsen 2005; Neves 2009; O'Neil 2015; Peng 2005; Rakowska 2015; Sebrechts 2005; Stern 1983);
- emotional support or client-led discussion (15 studies: Appels 2005; Blumenthal 2016; Burgess 1987; Elderen-van-Kemenade 1994; ENRICHD Investigators 2000; Gallacher 1997; Jones 1996; Mayou 2002; McLaughlin 2005; Peng 2005; Rahe 1979; Sebrechts 2005; Stern 1983; Turner 2013; Turner 2014); and
- cognitive challenge or cognitive restructuring techniques (19 studies: Black 1998; Brown 1993; Burell 1996a; Claesson 2005; ENRICHD Investigators 2000; Freedland 2009; Friedman 1982; Gulliksson 2011; Koertge 2008; Lie 2007; McLaughlin 2005; Merswolken 2011; Michalsen 2005; O'Neil 2015; Oldenburg 1985; Peng 2005; Rakowska 2015; Turner 2013; Turner 2014).

While the characteristics of psychological interventions were often described at length, most studies provided only a brief description of the comparator group. The most common form of comparator was either 'usual medical care' or a 'cardiac rehabilitation programme in addition to usual medical care'.

## Excluded studies

Of the 66 studies (76 publications) excluded from the new searches, 24 failed to meet our definition of a psychological intervention or were not delivered by trained personnel, 23 were not conducted with a suitable participant group, 10 had an inappropriate comparator group, four did not report results from RCTs, four had follow-up less than six months, and one had no suitable primary outcomes for this review. The list of excluded studies and reasons for exclusion are provided (see [Characteristics of excluded studies](#) table).

One study (one publication) was awaiting further information for classification (Ma 2010; see [Characteristics of studies awaiting classification](#)), and seven studies (11 publications) were potentially eligible, but the studies were still ongoing and no definitive results were available (Albus 2014; Barley 2014; Eckert 2010; Norlund 2015; Richards 2016; Spatola 2014; Tully 2016; see [Characteristics of ongoing studies](#) table).

### **Risk of bias in included studies**

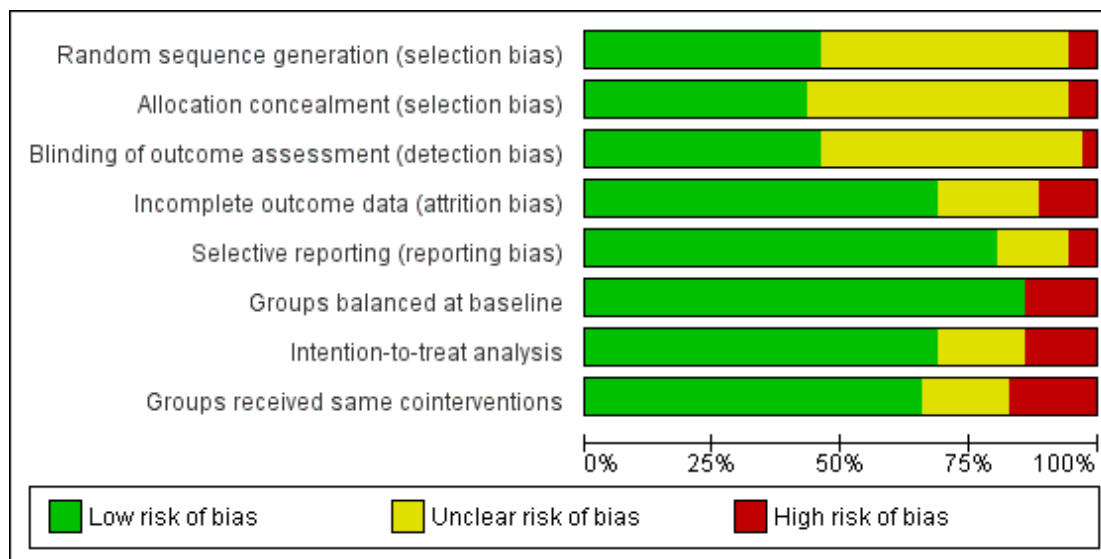
The risk of bias scores for individual studies are summarised in [Figure 2](#), and the methodological quality graph is presented in [Figure 3](#). For over half of the studies, the methods of random se-

quence generation, allocation concealment, and blinding of outcome assessment were unclear (with less than 10% coded definitively at high risk of bias). Two studies used quasi-randomisation methods, employing the date of admission to generate the allocation sequence (Elderen-van-Kemenade 1994; Oldenburg 1985). Unclear reporting of the other five quality criteria was much less common. Around one-quarter of all studies were at a high risk of bias due to incomplete reporting of outcome data, groups being unbalanced at baseline, not using an intention-to-treat analysis, or intervention and comparator groups varying in their exposure to cointerventions. Although the risk of bias of selected studies was often high, there was some evidence that more recent studies had improved in the quality of methods reported ([Figure 2](#)).

**Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Groups balanced at baseline	Intention-to-treat analysis	Groups received same interventions
Appels 2005	+	?	?	+	+	+	+	+
Black 1998	?	?	?	+	?	+	+	?
Blumenthal 2016	?	?	+	+	+	+	+	?
Brown 1993	?	?	?	?	?	+	?	+
Burell 1996a	?	?	?	?	?	+	?	+
Burgess 1987	?	?	?	?	+	+	+	?
Claesson 2005	?	+	?	+	+	+	+	+
Davidson 2010	+	+	+	+	+	+	+	+
Elderen-van-Kemenade 1994	+	+	?	+	+	+	+	+
ENRICHD Investigators 2000	+	+	+	+	+	+	+	+
Freedland 2009	+	+	+	+	+	+	+	+
Friedman 1982	+	?	?	+	+	+	+	+
Gallacher 1997	?	?	?	?	+	+	+	+
Gulliksson 2011	+	+	+	+	+	+	+	+
Jones 1996	?	+	+	+	+	+	+	+
Koertge 2008	+	+	+	+	+	+	+	+
Lie 2007	+	+	+	+	+	+	+	+
Mayou 2002	+	+	?	+	?	+	+	+
McLaughlin 2005	?	?	?	?	+	+	+	?
Merswolken 2011	+	?	+	+	+	+	+	?
Michalsen 2005	+	?	?	+	+	+	+	+
Neves 2009	?	?	?	+	+	+	?	+
O'Neill 2015	+	+	+	+	+	+	+	+
Oldenburg 1985	+	+	?	+	+	+	?	+
Oranta 2010	?	?	?	+	+	+	+	+
Peng 2005	?	?	?	+	+	+	+	?
Rahe 1979	?	?	?	+	+	+	+	+
Rakowska 2015	+	+	+	+	+	+	+	+
Roncella 2013	?	+	+	+	+	+	+	+
Schneider 2012	+	+	+	+	+	+	+	+
Sebregts 2005	+	+	+	+	+	+	+	+
Stern 1983	?	?	?	?	+	+	?	+
Turner 2013	+	+	+	+	+	+	?	+
Turner 2014	?	?	?	?	+	+	+	+
Van-Dixhoorn 1999	?	?	?	?	?	+	+	+

**Figure 3. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.**



## Effects of interventions

See: [Summary of findings for the main comparison Psychological intervention with or without other rehabilitation compared to control \(usual care/other rehabilitation\) for coronary heart disease \(third update\)](#)

### Primary outcomes

For clinical event outcomes, the length of follow-up ranged from six months to 10.7 years (median 12 months) and the levels of missing data at follow-up were low as the data were available from routine clinical records. For example, the overall level of attrition from the 23 studies contributing to pooled analysis of mortality data was 1.7% (median 0%, range 0% to 34.8%).

For studies measuring both clinical events and psychological outcomes, the psychological outcomes were often reported over shorter follow-up periods than clinical events, and the levels of missing data at follow-up were higher. Six of 19 studies reported attrition of 20% or higher for participants completing depression outcomes (Burgess 1987; ENRICHD Investigators 2000; Koertge 2008; McLaughlin 2005; Sebrechts 2005; Turner 2014), as did three of 12 studies reporting anxiety data (Burgess 1987; McLaughlin 2005; Turner 2014); however, this level of attrition was not observed in any of the eight studies reporting stress data.

The overall level of attrition of studies contributing to pooled analysis was 17.7% for depression (median 16.1%, range 0% to 31.6%), 9.1% for anxiety (median 8.7%, range 0% to 31%), and 9.4% for stress (median 2.3%, range 0% to 19.7%).

### Clinical events

Twenty-three trials reported total mortality (Analysis 1.1). There was no evidence of an effect in terms of risk reduction for total mortality (RR 0.90, 95% CI 0.77 to 1.05; participants = 7776;  $I^2 = 2\%$ ; GRADE = moderate).

Eleven trials reported cardiac mortality (Analysis 1.2). There was evidence of risk reduction in favour of the intervention (RR 0.79, 95% CI 0.63 to 0.98; participants = 4792;  $I^2 = 0\%$ ; GRADE = low), although there was some uncertainty in this finding. This analysis was rerun as a less conservative, fixed-effect model and the interpretation remained unchanged (RR 0.78, 95% CI 0.62 to 0.74).

Thirteen studies reported the rates of revascularisation (Analysis 1.3). Interventions showed no evidence of risk reduction for the occurrence of revascularisation (RR 0.94, 95% CI 0.81 to 1.11; participants = 6822;  $I^2 = 8\%$ ; GRADE = moderate).

Thirteen studies reported rates of non-fatal MI (Analysis 1.4),

which showed no evidence of risk reduction (RR 0.82, 95% CI 0.64 to 1.05; participants = 7845;  $I^2$  = 41%; GRADE = low).

### Psychological outcomes

Nineteen trials reported depression (Analysis 1.5). The meta-analysis found a reduction in depressive symptoms in the intervention group compared with the comparator group (SMD -0.27, 95% CI -0.39 to -0.15; participants = 5825;  $I^2$  = 69%; GRADE = low). Five studies also reported additional information on depressive symptoms (i.e. more than one tool assessing depression was scored) or whether or not a participant had been clinically diagnosed with depression, neither of which could be included in the meta-analysis (Table 1: Appels 2005; Freedland 2009; Mayou 2002; O'Neil 2015; Oranta 2010). Of these, three studies found benefits in favour of the intervention group (Appels 2005; Freedland 2009; Oranta 2010), with no difference observed in the remaining two studies (Mayou 2002; O'Neil 2015).

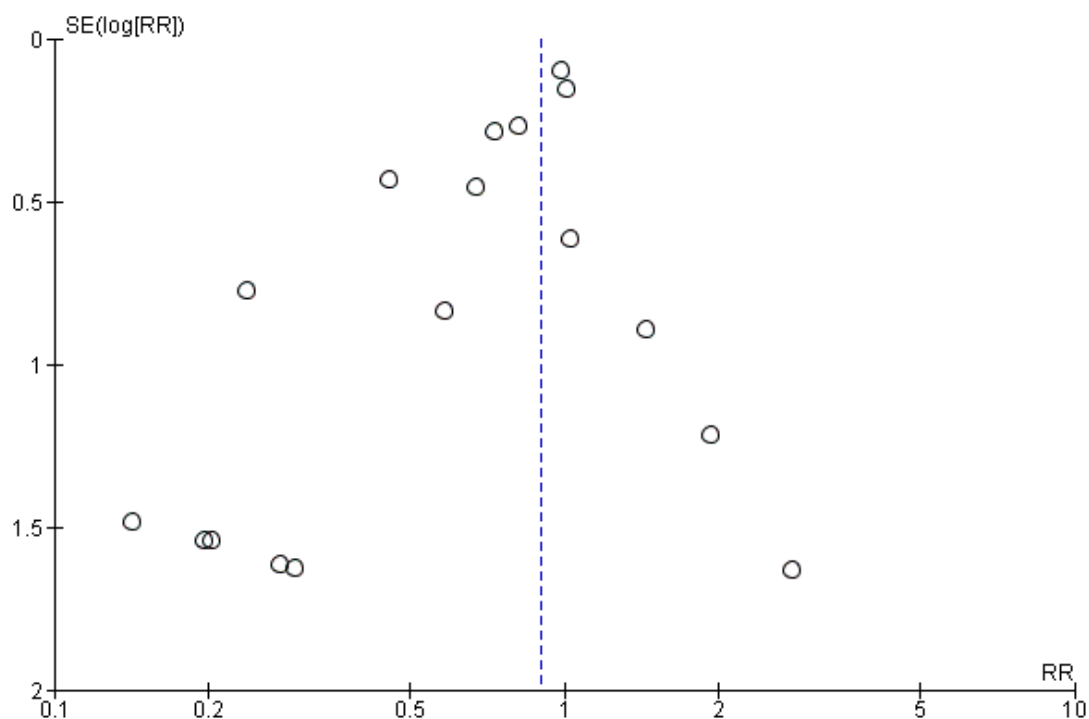
Twelve trials reported data on anxiety levels (Analysis 1.6) and eight trials reported data on stress levels (Analysis 1.7). There were reductions for both anxiety (SMD -0.24, 95% CI -0.38 to -0.09; participants = 3161;  $I^2$  = 47%; GRADE = low) and stress (SMD

-0.56, 95% CI -0.88 to -0.24; participants = 1251;  $I^2$  = 86%; GRADE = very low) in favour of the intervention group. However, there remains considerable uncertainty regarding treatment effects for all three psychological outcomes as the quality of evidence was either low or very low.

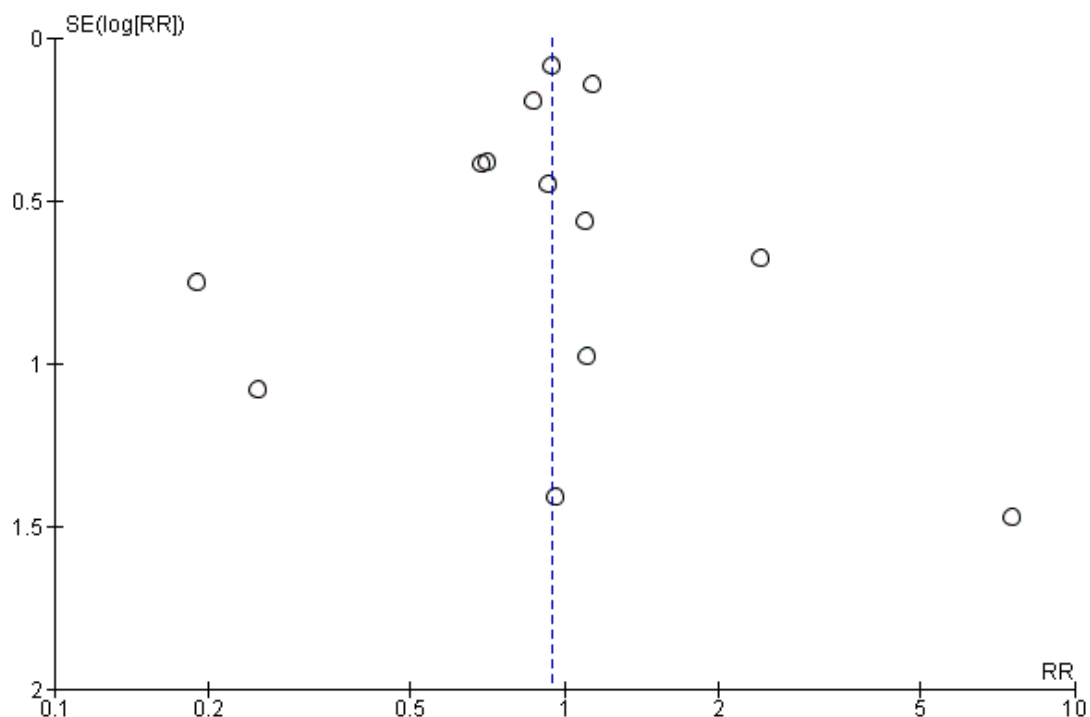
### Statistical heterogeneity and small-study bias

Inspection of  $I^2$  tests found significant levels of statistical heterogeneity in the meta-analyses of all psychological outcomes, but not for clinical events. Visual inspection of the funnel plots showed some evidence of asymmetry, and therefore of small-study bias, across trials for all participant-reported outcomes (depression, anxiety, stress) and cardiac mortality, although this was not apparent for the other clinical event data (Figure 4; Figure 5; Figure 6; Figure 7; Figure 8; Figure 9; Figure 10). However, we found no evidence of funnel plot asymmetry for the majority of primary outcomes (Egger test: total mortality  $P$  = 0.13, Figure 4; revascularisation  $P$  = 0.73, Figure 5; non-fatal MI  $P$  = 0.24, Figure 6; depression  $P$  = 0.14, Figure 7; stress  $P$  = 0.10, Figure 8), with the notable exceptions of cardiac mortality ( $P$  = 0.04, Figure 9) and anxiety ( $P$  = 0.012, Figure 10).

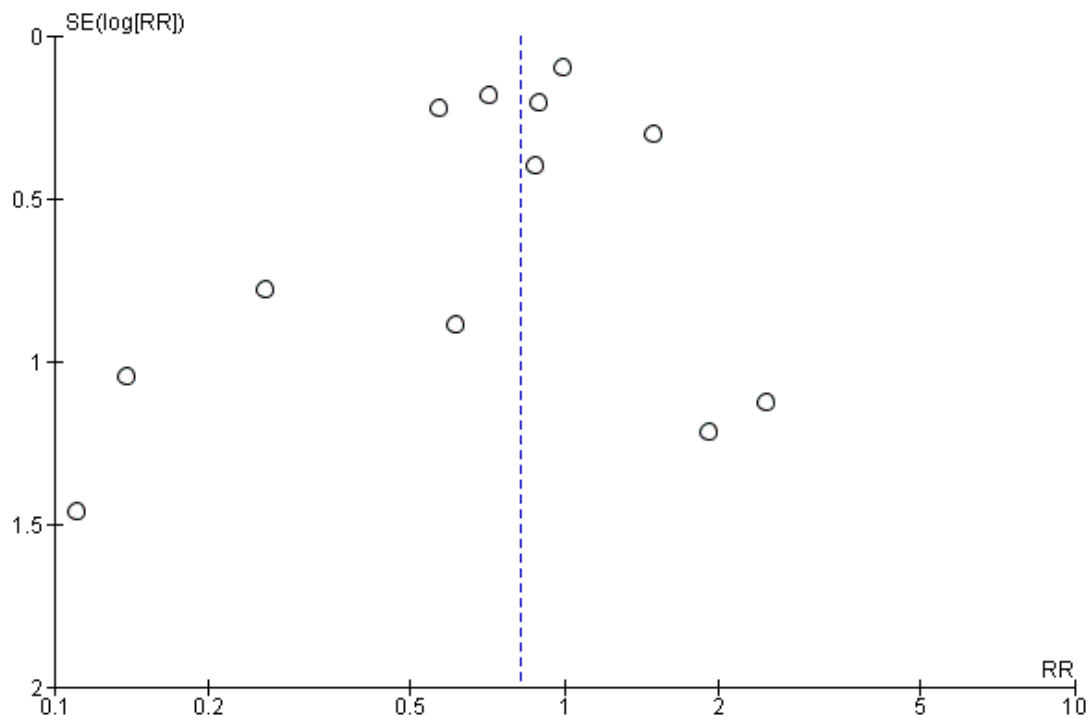
**Figure 4. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for total mortality (Analysis 1.1).**



**Figure 5. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for revascularisation (coronary artery bypass graft surgery and percutaneous coronary intervention combined) (Analysis 1.3).**

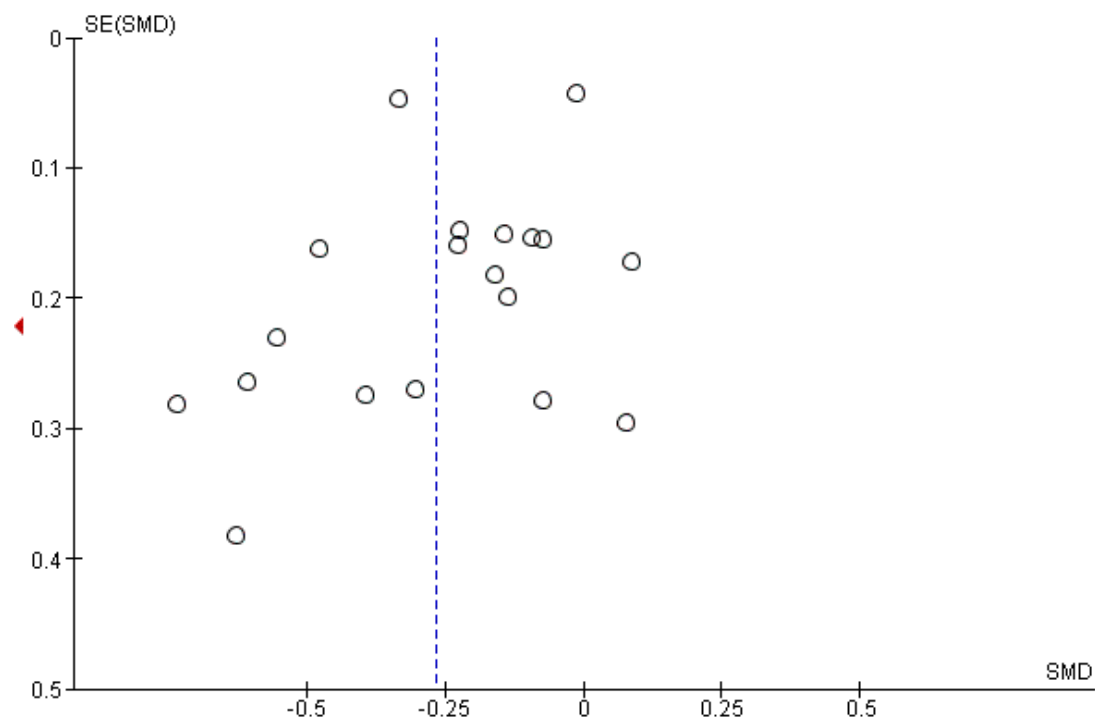


**Figure 6. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for non-fatal myocardial infarction (Analysis 1.4).**

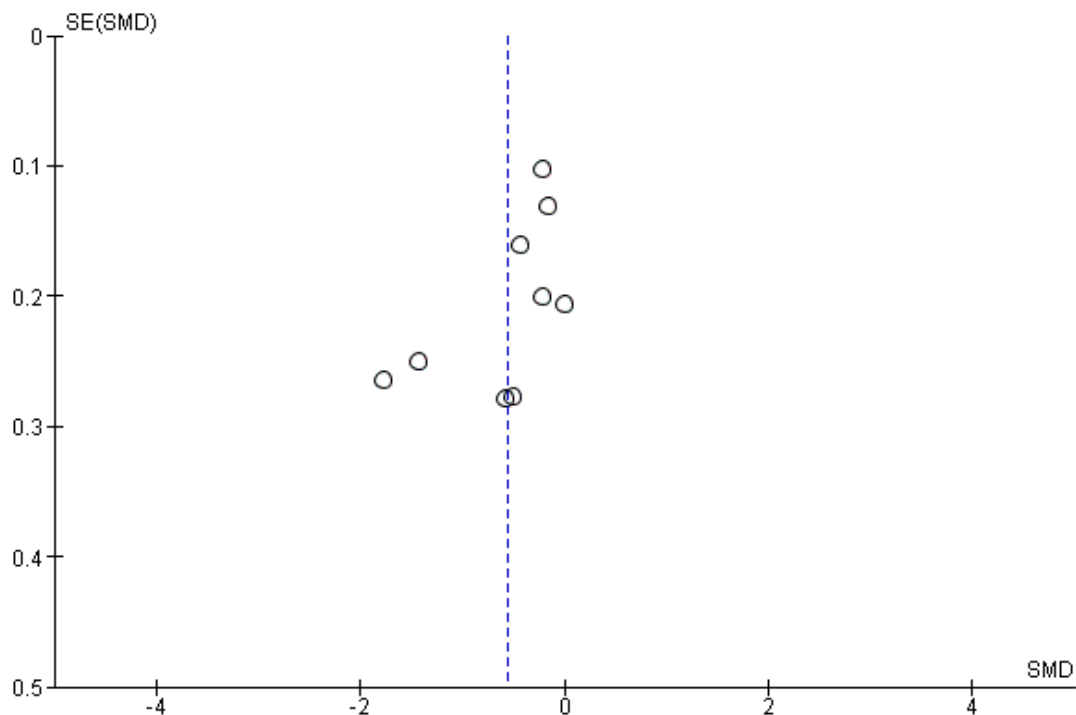




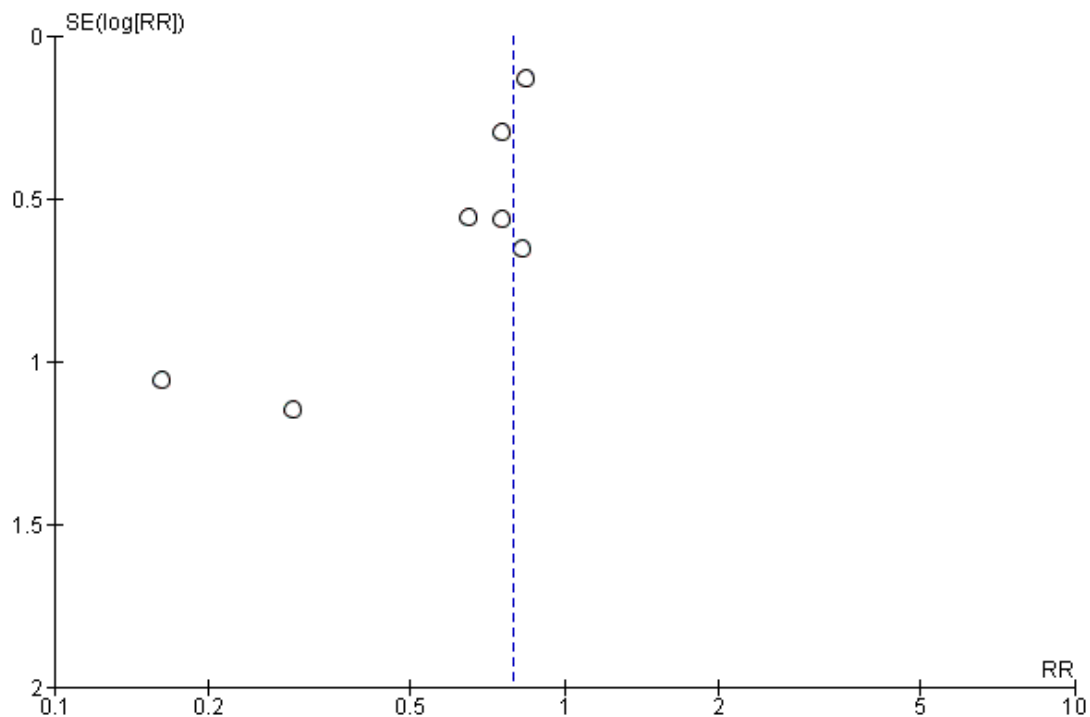
**Figure 7. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for depression (Analysis 1.5).**



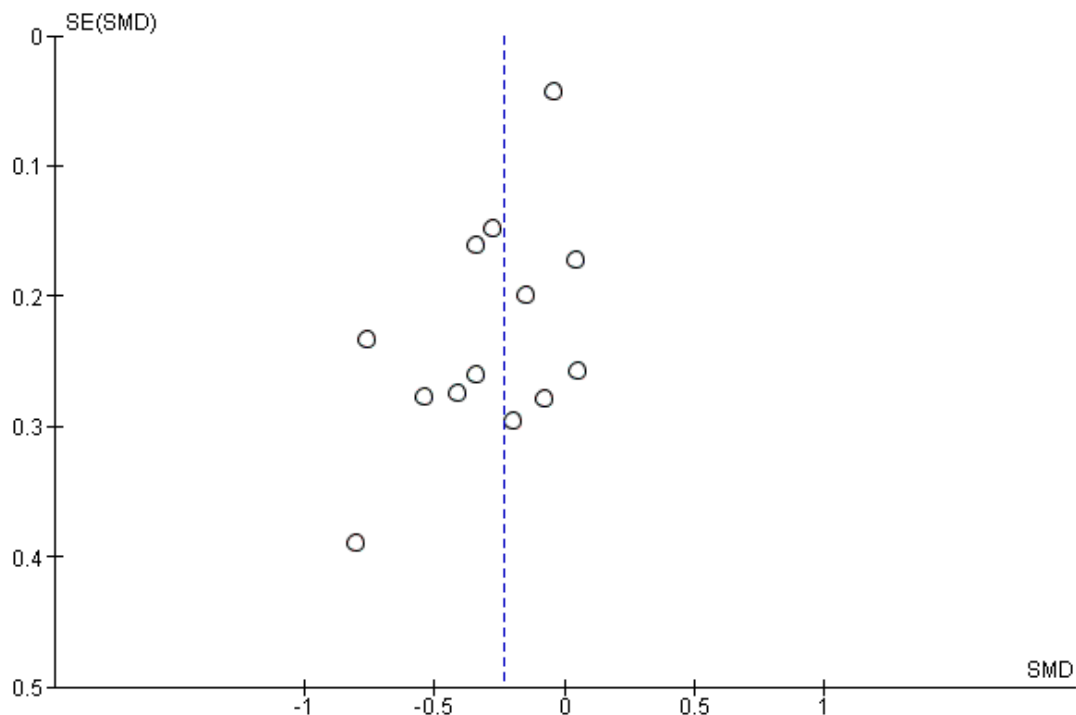
**Figure 8. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for stress (Analysis 1.7).**



**Figure 9. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for cardiac mortality (Analysis 1.2).**



**Figure 10. Funnel plot: psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation) for anxiety (Analysis 1.6).**



### Sensitivity analyses

We performed sensitivity analyses to assess potential bias arising from the inclusion of continuous outcome data (depression, stress) from [Roncella 2013](#), where the SD of the difference was calculated from the formula range/4. The exclusion of these data did not change the pooled estimates of effect or its precision to any notable degree (results not reported).

### Secondary outcomes

#### Health-related quality of life

With follow-ups ranging from six to 30 months, 10 studies reported HRQoL data ([Table 2](#); [Appels 2005](#); [Claesson 2005](#); [ENRICHD Investigators 2000](#); [Freedland 2009](#); [Lie 2007](#); [Mayou 2002](#); [Michalsen 2005](#); [O'Neil 2015](#); [Rakowska 2015](#); [Roncella 2013](#)). Direct comparisons between studies were difficult due to the different types of measures used to assess HRQoL. Notwithstanding this, vote counting found four studies reporting statistically significant improvements in at least one dimension

of HRQoL compared with the comparator group ([ENRICHD Investigators 2000](#); [Freedland 2009](#); [Rakowska 2015](#); [Roncella 2013](#)), and the remainder reporting no differences between groups ([Appels 2005](#); [Claesson 2005](#); [Lie 2007](#); [Mayou 2002](#); [Michalsen 2005](#); [O'Neil 2015](#)). Of the four studies reporting significant treatment effects, two studies reported improvements restricted to only the mental health-related or life satisfaction components of HRQoL (or both) ([ENRICHD Investigators 2000](#); [Freedland 2009](#)), a third study reported improvements in physical health-related components of HRQoL but not the emotional or social scores ([Roncella 2013](#)), while the final study reported improvements in both physical and mental health components of HRQoL ([Rakowska 2015](#)).

#### Other psychological outcomes

Other psychological outcomes, stratified by the type of outcome (distress, anger, Type A behaviour, vital exhaustion, hopelessness) are reported in [Table 1](#), with follow-ups ranging from 12 to 54 months. There was no evidence of between-group differences for measures of psychological distress ([Oranta 2010](#)), levels of anger ([Michalsen 2005](#)), or hopelessness ([Freedland 2009](#)) for individual

studies measuring these outcomes. Two studies measured Type A behaviour, as assessed by a clinician rating a videotaped structured interview. Both studies found some evidence of a reduction in Type A behaviours (or some of its subcomponents) in the intervention group compared with comparators (Friedman 1982; Sebrechts 2005). Finally, the four studies comparing participants' reports of vital exhaustion as an outcome found conflicting evidence, with Claesson 2005 and Koertge 2008 reporting some improvement in the intervention group, while this was not observed by Sebrechts 2005 or Roncella 2013.

### Return to work

Three early studies reported data on participant return to work across a 12-month follow-up period (Burgess 1987; Oldenburg 1985; Stern 1983). Burgess 1987 reported that 68/76 (88%) of the intervention group and 68/77 (88%,  $P > 0.10$ ) of the comparator group had returned to work, while Oldenburg 1985 reported that 10 participants (90%) of the intervention group who were working prior to their cardiac event versus nine participants (56%) of comparator group had returned to work ( $P$  value not reported). Stern 1983 reported no differences in the proportions of people returning to work between intervention and comparator groups, at either the levels of working prior to their MI, or at a reduced level (i.e. part-time), although detailed data were not presented.

### Cost-effectiveness data

Only two studies reported any type of economic evaluation alongside trial data (Davidson 2010; Van-Dixhoorn 1999), although two ongoing studies include an economic evaluation as part of their protocol (Albus 2014; Barley 2014). Van-Dixhoorn 1999 reported a limited evaluation of intervention costs to an examination of hospital costs arising from cardiac-related hospital readmissions across a five-year follow-up. In a secondary analysis, the authors reported that the extra costs of individual relaxation training sessions (the intervention) was outweighed by the benefits in terms of a reduction in medical consumption (30% reduction in the number of days in hospital in the intervention group and 46% reduction in costs due to reduced readmissions for cardiac surgery). Davidson 2010 (reported in Ladapo 2012) examined HRQoL, healthcare utilisation, and costs of enhanced psychological care compared to usual physician care. The mean total healthcare costs (psychotropic medicines, ambulatory care, hospitalisations) totalled USD1857 for the intervention group and USD2797 for usual care (adjusted difference -USD1229 per participant, 95% CI -USD2652 to USD195,  $P = 0.09$ ), with a 98% probability that this approach would be considered cost-effective if a willingness to pay threshold of USD30,000 per quality-adjusted life-year gained was applied.

### Meta-regression analyses

We limited our exploration of study heterogeneity to a series of univariate meta-regression analyses and used the four most commonly reported outcomes: total mortality (results presented in Table 3); cardiac mortality (Table 4); depression (Table 5); and anxiety (Table 6). Consistent with the lack of statistical heterogeneity in total mortality and cardiac mortality across the trials, none of the predictor variables were statistically significant in meta-regression analyses for either outcome.

Despite the higher levels of statistical heterogeneity observed across studies for the outcomes of depression and anxiety, meta-regression found only one variable that significantly predicted the study effect size for each of the variables. For depression, studies combining pharmacology for the psychological disorder (where deemed clinically appropriate) alongside psychological intervention were significantly more effective ( $\beta = -0.51$ ,  $P = 0.003$ ) than those studies which did not. There was also a non-significant trend suggesting that studies which recruited participants with CHD and an established psychological disorder may be more effective ( $\beta = -0.20$ ,  $P = 0.10$ ) than those delivered to unselected populations. In contrast, meta-regression of anxiety data found more robust evidence that studies targeting participants with CHD and a psychological disorder were more effective ( $\beta = -0.28$ ,  $P = 0.03$ ) than those that did not. There was also a non-significant trend suggesting that psychological interventions that included input from family members may be less effective ( $\beta = 0.24$ ,  $P = 0.06$ ) than those that did not.

### Quality of evidence from randomised controlled trials

We rated the quality of the evidence using the GRADE method (Schünemann 2011). The quality of the evidence varied widely by outcome and ranged from very low to moderate (Summary of findings for the main comparison). The evidence for all outcomes was downgraded due to poor reporting of random sequence generation, allocation concealment, or blinding of outcome assessors in at least 50% of the studies which contributed data to the evidence. In addition, some outcomes were downgraded for inconsistency (depression and stress), imprecision (non-fatal MI and stress), or evidence of publication bias (cardiac mortality and anxiety).

## DISCUSSION

### Summary of main results

We found no evidence that psychological interventions targeting stress or emotional disorders, compared with usual care, reduced total mortality or the risk of revascularisation in participants with CHD, although the GRADE quality of evidence was moderate indicative of uncertainty. There was also no evidence of a reduced

risk of non-fatal MI, although there was evidence of fewer deaths attributed to cardiac causes among participants receiving a psychological intervention. However, the quality of evidence was low according to GRADE for both of these effects. While this indicates considerable uncertainty, the potential impact on quality may still be of clinical interest and warrants further investigation. In contrast, we found that psychological interventions resulted in small to moderate improvements in the levels of depressive symptoms (GRADE: low), anxiety (low), and stress (very low), although the quality of evidence was either low or very low. There was also evidence of small-study bias for the outcomes of anxiety and cardiac mortality.

A narrative review using vote counting was used to explore the impact of psychological interventions on secondary outcomes. No study reported that psychological interventions were deleterious to health or wellbeing. However, the conclusions that can be drawn were limited due to the differences in outcome measures used, combined with small numbers of studies reporting HRQoL and other psychological outcomes (Type A behaviour, anger, distress, vital exhaustion, hopelessness); very few studies presented data on participant return to work or cost-effectiveness data. Notwithstanding this, there is some evidence of a positive effect on HRQoL (in four of eight studies), and there was insufficient evidence regarding whether psychological treatments facilitated return to work. However, direct comparisons are problematic as different measures were used between studies or contradictory effects were identified for the different subdomains of the same measure (e.g. benefits restricted to physical as opposed to mental health, or vice versa) (or both). The two studies which conducted economic evaluations both concluded that psychological therapies were likely to be cost-effective, although this evidence requires replication in future research.

An exploratory analysis to identify potential modifiers (e.g. target population, treatment aims or components (or both), cointerventions) of intervention effectiveness failed to identify any predictor variables for the clinical outcomes of total and cardiac mortality. Given the lack of statistical heterogeneity observed in the meta-analyses for these variables, combined with the small number of included studies and relatively short participant follow-up period, this finding was expected. This finding was also consistent with a similar analysis presented in the previous update (Whalley 2011). When analysing the two psychological outcomes of depression and anxiety (where there was considerably greater statistical heterogeneity in the respective meta-analyses), only a limited number of predictor variables were of importance in meta-regression models. For depression, the adjunct use of pharmacological therapy for the underlying psychological condition (where deemed clinically appropriate) increased intervention effectiveness ( $\beta = -0.51$ ,  $P = 0.003$ ) compared with interventions that did not. For anxiety, psychological interventions which recruited participants with CHD and an underlying psychological disorder ( $\beta = -0.28$ ,  $P = 0.03$ ) appeared more effective than those delivered to un-

selected populations. The following trends ( $P \leq 0.10$ ) were also observed, although these data should be interpreted with caution. For depression, it is possible that interventions targeting participants with CHD and an established psychological disorder may be more effective ( $\beta = -0.20$ ,  $P = 0.10$ ) than those delivered to unselected populations. Similarly, there was a trend towards interventions that involved family members being less effective ( $\beta = 0.24$ ,  $P = 0.06$ ) when managing anxiety symptoms than those with no family involvement.

## Overall completeness and applicability of evidence

The scope of this review was limited in its design in three specific ways, by including only those studies where: the direct effects of a psychological intervention was tested against a comparator; the psychological intervention aimed to alleviate psychological symptoms or distress; and where outcomes were reported at a minimum of six months postrandomisation. These limitations in scope were crucial in addressing the specific question of what is the 'added value' of emotion-focused psychological interventions for people in the contemporary management of people with CHD. Psychological care is deemed to be a core component of CR (BACPR 2014; Lichtman 2014; Piepoli 2014), although there is considerable uncertainty regarding what types of intervention should be provided, and for what purpose. We also focused on longer-term outcomes to improve the clinical relevance of such findings.

By excluding psychological interventions that were primarily aimed at achieving reductions in cardiac risk factors (e.g. smoking cessation, diet, and physical activity), this review aimed to provide more definitive evidence regarding interventions tackling the emotional and stress-related sequelae for people living with CHD. Despite this focus, there remained considerable clinical heterogeneity in terms of the treatment aims and components of interventions tested and the populations targeted (e.g. with or without targeting of underlying psychological conditions).

## Quality of the evidence

The details of intervention and trial methodology were often poorly reported, resulting in the quality of evidence being assessed as moderate at best. Other reasons for downgrading the quality of evidence included the risk of bias and imprecision. The lack of methodological detail limited our ability to assess risk of bias, despite using recommended criteria and tools (Higgins 2011). This review was also composed mainly of relatively small studies, which might pose a high risk of bias and have the potential to overestimate the effect of psychological treatment, particularly when combined with selective outcome reporting and the lack of blinding of outcome assessments. Some psychological outcomes also required the imputation of data due to the lack of numerical information

reported. While there was no evidence of statistical heterogeneity ( $I^2$  tests) in the meta-analyses of clinical events, there was significant heterogeneity for the pooling of all the psychological outcomes and these data should be interpreted with caution.

The other area of potential risk of bias was the potential for imbalance of cointerventions received by intervention and control participants. Although we specifically selected studies that tested the direct effects of psychological interventions, excluding studies where there appeared an imbalance in cointerventions based on independent review by two authors, the decision was ultimately one of judgement based on the description of the intervention and control groups provided by the authors. A common feature of the literature was a lack of detailed description of the control condition.

### Potential biases in the review process

We conducted all stages of this review update in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011) and complied with all “mandatory” requirements of The Methodological Expectations of Cochrane Intervention Reviews (MECIR) (Chandler 2013). However, this review is subject to a number of potential limitations, such as the issue of poor reporting of methods noted previously. Regarding the completeness of data, attrition rates for clinical event outcomes were negligible as this information was captured from clinical records. However, most of the trials were relatively small and had short-term follow-up, so that the potential number of deaths and cardiac events reported by the majority of trials was small. Psychological outcomes were also observed over relatively short time frames, and the attrition rates in pooled analyses were higher (17.1% depression, 9.1% anxiety, 9.4% stress) as these data were self-reported by participants.

This updated review identified more complete information on participant age, ethnicity, cardiac indication, and psychopathology at baseline. Most studies reported participant age, sex, and CHD indication, but far fewer reported on ethnicity or the presence of a psychopathology. From the information reported, it appeared that the majority of participants were men, recruited post-MI, and from studies taking place in high-income nations (Europe and the USA). As such, it is unclear whether our findings generalise to women, or to the population in general. In addition, although we had amended the study inclusion criteria to better reflect current practice whereby more diverse participant populations are using CR services, in reality only two studies included participants with conditions other than ACS or angina, and the proportions of other cardiac conditions in the resultant samples were considerably less than the selection criterion stating a sample threshold of less than 50% that we had imposed a priori.

Finally, the lack of reporting of study interventions also made it difficult to categorise and compare the psychological interventions under investigation across studies. Many of the psychologi-

cal interventions under investigation were multifactorial, addressing numerous treatment aims, and including multiple treatment components. Although our meta-regression analyses did identify a single predictor of treatment effects for depression and anxiety outcomes, the significant heterogeneity observed in pooled analyses of depression and anxiety remains largely unexplained.

### Agreements and disagreements with other studies or reviews

The findings of this third update are broadly consistent with the analyses presented on primary outcomes in the previous update (Whalley 2011). However, the meta-regression findings did not replicate the univariate analysis presented previously for the outcome of depression. It had previously been found that treatments aiming to treat Type A behaviours including anger and hostility were more effective at reducing depressive symptoms than other interventions, while interventions including risk-education information, client-led discussion, and emotional support as core therapeutic components, or where family members were included in the treatment process, were less effective. The fact we did not replicate these findings is likely to be attributable to the inclusion of a number of new studies reporting psychological outcomes, combined with the exclusion of data from two studies that had previously contributed data to these analyses (Hofman Bang 1999; Peng 2005).

From the wider literature, two systematic reviews synthesised evidence exploring whether psychological interventions were effective at alleviating psychological morbidity for people with CHD (Dickens 2013; Welton 2009). Both reviews used multivariate meta-regression techniques to identify characteristics of interventions that may influence treatment effects. Direct comparisons between all the existing systematic reviews are problematic due to important differences in the methodology and definitions applied. For example, Welton 2009 selected studies that included multifactorial interventions (e.g. psychological therapies, exercise programmes) compared with usual care, which limits the degree to which the direct effects of psychological therapies can be tested outside of a meta-regression framework. Consistent with our approach, Dickens 2013 selected studies where the direct effects of psychological interventions could be tested, but studies with any length of follow-up (ranging from five days to 12 months) were included, and mortality or cardiac morbidity were not synthesised. In the meta-regression analyses presented, both Welton 2009 and Dickens 2013 applied different taxonomies to define potential explanatory components of psychological interventions, which also varied from our approach. Despite the substantial differences in study methods, there was some consistency in findings from the wider literature and our review findings.

Welton 2009 characterised psychological interventions into six main groups (usual care, educational, behavioural, cognitive, relaxation, and psychological support), prior to conducting meta-

regression modelling. Data from 51 studies reporting relevant outcomes were analysed (36 studies reported all-cause mortality, 19 reported depression). Broadly consistent with our findings, [Welton 2009](#) found no evidence that psychological interventions (cognitive techniques, relaxation, or psychological support) or educational interventions reduced total mortality or cardiac mortality, although behavioural interventions (including exercise) appeared most effective. However, unlike our findings, 'psychosocial support' was effective at reducing rates of non-fatal MI. In terms of psychological outcomes, [Welton 2009](#) also found that psychological interventions appeared effective at reducing standardised mean anxiety scores. However, this review also reported that interventions with cognitive or behavioural (or both) components were associated with reduced standardised mean depression scores; a finding inconsistent with our data (which found no evidence that cognitive interventions, or interventions also targeting behavioural change, were more effective).

[Dickens 2013](#) categorised interventions into 11 groups (general education, general discussion, skills training, exercise, behavioural therapy, relapse prevention, problem solving, cognitive behavioural therapy, increased social support, relaxation, and biofeedback). Analysing data from 62 studies (17,397 participants), consistent with our findings, found a small but statistically significant improvement in depression (SMD 0.18, 95% CI 0.12 to 0.24; 64 trial arms) and there was evidence of statistical heterogeneity ( $I^2 = 51.4\%$ ). Meta-regression identified certain treatment components with small beneficial effects, including general education, problem solving, skills training, exercise, cognitive behavioural therapy, and relaxation. In a subgroup analysis restricting sampling to studies targeting people with CHD and depression only, there was a small effect observed in favour of psychological interventions (SMD 0.21; 12 trial arms).

More recently, rather than evaluating the effectiveness of psychological interventions (in isolation, or more commonly as multifactorial interventions), there has been considerable interest in evaluating the impact of collaborative care for people with CHD and depression. The focus of collaborative care is not to evaluate the effectiveness of individual psychological therapies per se, but rather to ensure that people with CHD and depressive symptoms receive best practice psychological care through the appropriate assessment, symptom monitoring, referral to psychological therapists, and, where needed, pharmacological interventions. The underlying assumptions with these models of care are that the psychological approaches used in general populations are also applicable to people with CHD and depressive symptoms. Psychological care is delivered by a care manager, who works with the person over a period of time to tailor their preferences for care with recommendations based on their symptoms and previous experiences; in some cases, the care manager also provides elements of psychological therapy. One systematic review by [Tully 2015](#) synthesised data from six RCTs (1284 participants randomised to either collaborative care or a comparator group). Once again, there was no

evidence of sustained reductions in major adverse cardiac events (including mortality or morbidity) arising from collaborative care, although there were small reductions in the short term (three to 12 months) for depressive symptoms (SMD -0.31,  $P < 0.00001$ ), anxiety symptoms (SMD -0.36,  $P < 0.0001$ ), and mental HRQoL improved (SMD 0.24,  $P < 0.003$ ).

## AUTHORS' CONCLUSIONS

### Implications for practice

There is considerable evidence that negative emotional states, such as anxiety ([Tully 2014](#)) and depression ([Dickens 2013](#)), and long-term stress ([Stephoe 2012](#)) are related to poor cardiac outcomes. However, there remains uncertainty in the theoretical and empirical literature on the causal mechanisms linking mood disorders or long-term stress to worse clinical outcomes, and of which subgroups of people may be at particularly high risk of poor outcomes and who might be targeted by novel interventions ([Dickens 2015](#); [Stephoe 2012](#); [Tully 2014](#)). Within this context, it is unsurprising that most studies have evaluated multifactorial psychological interventions as no single causal mechanism is likely to fully explain the complex relationship between coronary heart disease (CHD), mood states, and stress, and how this might have a wider impact on behavioural interventions targeting cardiac risk factor reduction.

Despite this, it remains clear that psychological interventions tackling stress or negative mood (or both) yield small reductions in psychological symptoms in participants with CHD, irrespective of whether or not they are identified with a psychological disorder prior to treatment. This updated Cochrane Review (replicating some of the findings reported by [Whalley 2011](#)), reported small-to-moderate effects on cardiac mortality, and symptoms of depression or anxiety in favour of psychological treatments, although applying the GRADE methodology in this update identified the evidence to be of low quality. For the first time, we synthesised the effects of psychological interventions on the outcome of participant-reported stress levels, which also demonstrated benefits in favour of the intervention, although once again there is considerable uncertainty in this result. However, unlike the previous update, our meta-regression analysis identified far fewer predictors of treatment effects. Although we found psychological therapies targeting participants with an established psychological condition at baseline might be more effective at relieving anxiety symptoms (and possibly depressive symptoms), these findings are exploratory. It remains possible that the potential impact of psychological interventions targeting people with psychological disorders is underestimated in meta-regression analysis, as 10 trials recruiting unselected participants from cardiac populations reported some levels of psychopathology as part of the baseline characteristics of study



participants (3.8% to 53% with depressive symptoms, 32% to 53% with anxiety), 10 studies did not report these characteristics, and only three studies excluded people with psychopathology. Notwithstanding this, there is currently no robust evidence from this review that cardiac rehabilitation programmes should only target psychological interventions at people with established psychological disorders.

Since the first published review in 2004, there has also been a change in the emphasis and direction of research. A considerable body of work has demonstrated the effectiveness of specific psychological interventions in defined population samples (e.g. cognitive behavioural therapy, or behavioural activation for people with depression). While such evidence may not be derived specifically from samples of people with CHD, current best practice guidelines in the UK and Europe recommend that people with physical health problems and mood disorders are referred to existing psychological services for the management of their mental health (BACPR 2014; NICE 2009; Piepoli 2014). Consistent with this, research is increasingly focusing on the effectiveness of interventions designed to identify, monitor, and support people with CHD and mental health problems rather than on the effectiveness of specific therapeutic strategies (e.g. collaborative care). Such interventions seek to personalise mental health care, ensuring it is tailored around an individual's specific needs and preferences, which may include offering people psychological therapies or pharmacological management (or both) for their psychological condition.

### Implications for research

Given the significant clinical and statistical heterogeneity observed in the studies selected, which is for the most part unexplained through meta-regression analysis, there appears to be little benefit in continuing to update this review in its current form. Although we know that psychological interventions tend to have modest, but significant effects on reducing psychological symptoms, this review cannot adequately address the questions of what components work, at what point in the patient's journey, and for whom. The application of GRADE methodology to this latest update also demonstrated that the quality of evidence is mostly low. Future research and evidence synthesis should become more focused, aiming to clarify the evidence for subgroups of people at particularly high risk of poor outcomes (e.g. people with established psychopathology), and on exploring the effectiveness of specific therapies (e.g. stress management techniques, different therapeutic approaches to mood management) and management strategies (e.g. collaborative mental healthcare) rather than seeking to pool clinically heterogeneous data from complex multifactorial interventions with mixed populations.

It is important that future research should focus on developing interventions with the potential to improve both cardiac and mental health outcomes (Dickens 2015). There remains a need to eval-

uate the impact of different types of psychological interventions on a range of participant-reported outcomes (e.g. psychological symptoms, health-related quality of life) and clinical events, and to evaluate its cost-effectiveness. The reporting of trials, and particularly the descriptions of psychological interventions tested and the psychological status of participants at baseline, requires improvement. Notwithstanding this, there remain many areas of uncertainty and our understanding of treatment effects are unlikely to become clearer until there is greater clarity between theoretical/causal mechanisms of CHD and psychological disorders. The majority of studies included in this review assessed the impact of multifactorial psychological interventions, with only a minority test the effectiveness of specific therapies (e.g. Van-Dixhoorn 1999 and Blumenthal 2016 testing the effect of stress management). This is essential so that the likely therapeutic actions of *specific* psychological therapies can be identified, and clearer links as to how this might lead to beneficial outcomes for people with CHD can be made. We identified a number of ongoing trials that appear to be directly addressing some of these uncertainties (Norlund 2015; Richards 2016; Spatola 2014). There are also a number of trials underway testing the effectiveness of collaborative care models of mental healthcare for people with heart disease (Albus 2014; Barley 2014; Eckert 2010).

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- \* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Appels 2005

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Netherlands.</p> <p><b>Dates participants recruited:</b> July 1996 to April 2001.</p> <p><b>Maximum follow-up:</b> 18 months.</p> <p><b>Follow-up schedule:</b> 6 and 18 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged 35-68 years, who felt exhausted after being successfully treated by PCI, assessed via the Maastricht Questionnaire (MQ 1987; cutoff of 14) and the Maastricht Interview for Vital Exhaustion ('Maastricht Questionnaire'; cutoff of 7 positive responses)</p> <p><b>Exclusion criteria:</b> severe somatic or mental comorbidity (e.g. kidney insufficiency, <math>\geq 3</math>-year history of major depression), somatisation disorder, fibromyalgia or chronic fatigue, participation in another behavioural rehabilitation programme, unsuccessful treatment for a recent depression or panic disorder, inability to speak Dutch</p> <p><b>Indication (% participants):</b> post PCI (100%) including stable angina (13%), unstable angina (57%), MI (18%), post-MI angina (10%)</p> <p><b>Psychopathology:</b> major depression (14%).</p> <p><b>Number randomised:</b> total: 710; intervention: 366; comparator: 344.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: <math>53.6 \pm 7.2</math> years; comparator: <math>53.1 \pm 7.4</math> years</p> <p><b>Men:</b> total: 77%; intervention: 80%; comparator: 74%.</p> <p><b>Ethnicity (% white) :</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> group discussions were used to identify stressors in the family and work domain, and to assist participants in coping with these stressors. Recovery was promoted by discussing the minimum and maximum length of resting time, by doing relaxation exercises designed to make rest more efficient, by stimulating physical exercise, and by assigning homework. Group discussions were used as the main basis of the EXhaustion Intervention Trial intervention to ensure an optimal match between the needs and demands of the participants and the content of the programme. Counsellors acted mainly as facilitators of the group discussions</p> <p><b>Treatment targets:</b> exhaustion, stress, anxiety, Type A behaviours.</p> <p><b>Components:</b> relaxation, client-led discussion, empathy and social support, self-monitoring/self-awareness, and individually tailored relaxation</p> <p><b>Treatment setting (number of sites):</b> hospital (4).</p> <p><b>Modality (group size):</b> group (6 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 2 hours;</li> <li>frequency/number of sessions: weekly for 10 weeks then monthly for 4 months;</li> <li>total duration: 28 contact hours over 26 weeks.</li> </ul> <p><b>Delivered by:</b> experienced psychotherapists or clinical psychologists.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> all groups were offered the possibility to meet with a cardiologist, dietitian, and a health educator if they wanted to have more information about medical</p>

	aspects, nutrition, and smoking cessation <b>COMPARATOR:</b> standard care. <b>Cointerventions:</b> referral to a physical rehabilitation programme at 1 centre	
Outcomes	Revascularisation (CABG and PCI). HRQoL (MacNew Questionnaire). Vital exhaustion (Maastricht Questionnaire).	
Source of funding	Dutch Heart Foundation and the Netherlands Organization for Health Research and Development	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Used a 'computerised random number generator'. Groups were unbalanced for sex and HRQoL score
Allocation concealment (selection bias)	Unclear risk	Once a block of 12 qualifying participants was formed, participants were randomised to the intervention group or the usual-care control group individually by a computerised random-number generator maintained in the EXhaustion Intervention Trial coordination center (Maastricht). Treatment assignment was never unmasked by previous assignments to avoid selection bias that results from research staff being able to predict the next treatment assignment
Blinding of outcome assessment (detection bias)	Unclear risk	Morbidity results were obtained by an assessor blinded to group assignment; unclear for interview outcomes
Incomplete outcome data (attrition bias) All outcomes	Low risk	All treatment group comparisons were based on intention-to-treat approach principles. All participants allocated to the intervention group were included in the analyses, irrespective of their compliance. Missing values at 6 and 18 months were replaced by the last observed value

**Appels 2005** (Continued)

Selective reporting (reporting bias)	High risk	Data on clinical diagnosis of depression were mentioned in the protocol as having been collected at baseline and 18 months, but 18-month comparisons not reported - it was unclear whether the authors considered depression as an outcome. 6-month vital exhaustion data not reported
Groups balanced at baseline	Low risk	"The groups were balanced in terms of all medical, demographic, and psychological characteristics except gender."
Intention-to-treat analysis	Low risk	"All treatment-group comparisons were based on intention-to-treat approach principles."
Groups received same cointerventions	High risk	"Usual care consisted of the care regularly given in the 4 centres. It included routine check-ups in all centres and referral to a physical rehabilitation programme in 1 centre."

**Black 1998**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> cardiac rehabilitation clinic (1).</p> <p><b>Maximum follow-up:</b> 21 months.</p> <p><b>Follow-up schedule:</b> programme exit, 3, 6, 9, and 21 months.</p>
Participants	<p><b>Inclusion criteria:</b> CAD documented by cardiac catheterisation or MI, hospitalisation for a coronary event such as unstable angina, AMI, PTCA, or CABG surgery within 3 months of referral into cardiac rehabilitation, and willingness to be screened and give informed consent to participate in the trial</p> <p><b>Exclusion criteria:</b> aged &gt; 80 years, judged to be mentally incompetent, or currently undergoing treatment by a psychiatrist or psychologist</p> <p><b>Indication:</b> acute CHD events (MI, revascularisation, angina; % NR).</p> <p><b>Psychopathology:</b> psychological distress, Global Severity Index SCL-90-R <math>\geq</math> 63 (100%)</p> <p><b>Number randomised:</b> total: 60; intervention: 30; comparator: 30.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 60.2 <math>\pm</math> 10.7 years; intervention: NR; comparator: NR.</p> <p><b>Men:</b> total: 88%; intervention: NR; comparator: NR.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> 1-7 weekly sessions dealing with issues identified in the treatment plan. Intervention included <math>\geq</math> 1 of the following: individualised relaxation training; stress management; efforts to reduce behavioural risk factors; efforts to improve compliance with medical, dietary, and exercise regimens; and cognitive-behavioural interventions</p>

	for identified sources of distress, such as anxiety, depression, and hostility <b>Treatment targets:</b> behaviour change, stress management, anxiety, depression, and Type A behaviour <b>Components:</b> guidance on behaviour change, relaxation, cognitive challenge/restructuring, psychoactive pharmacological drugs as required <b>Treatment setting (number of sites):</b> cardiac rehabilitation clinic (1). <b>Modality (group size):</b> individual. Unclear whether family included. <b>Dose:</b> <ul style="list-style-type: none"><li>length of session: NR;</li><li>frequency/number of sessions: weekly/1-7;</li><li>total duration: 4 contact hours (median) over 7 weeks.</li></ul> <b>Delivered by:</b> clinical behavioural psychologist. <b>Follow-up further reinforcement:</b> NR. <b>Cointerventions:</b> consistent with a counselling model, psychoactive drugs that were considered essential were prescribed accordingly. Participants were also offered comprehensive cardiac rehabilitation as per usual care <b>COMPARATOR:</b> usual care control consisting of comprehensive cardiac rehabilitation (8-week programme) involving monitored exercise sessions 1-3 times per week. The participants were also offered a series of educational lectures, which included information about Type A behaviour and stress management, a 2-part support group meeting for participants and spouses or significant others, and individualised dietary counselling <b>Cointerventions:</b> NR.	
Outcomes	Total mortality. Morbidity - MI, CABG, PCI. Anxiety (distress/Global Severity Index from SCL-90-R). Depression (subscale from SCL-90-R).	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Stated that the participants were randomly allocated. No further details
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	All outcomes described in the methods were reported in the results section

**Black 1998** (Continued)

Selective reporting (reporting bias)	Unclear risk	Not described.
Groups balanced at baseline	Low risk	“There were no statistically significant differences between the experimental groups in terms of scores on the SCL-90-R subscales, age, lipid profiles, smoking history at index event, diabetes, hypertension, family history of CHD before age 50, use of antilipidemics, anticoagulants (including aspirin), and betablockers (before or after MI), number of rehabilitation-exercise sessions per week, educational level, marital status, or such cardiac factors as type of index event, number of diseased vessels, or left-ventricular ejection fraction.”
Intention-to-treat analysis	Low risk	Intention-to-treat analysis was not described, but was implied by the following sentence: “Because of the large number of crossovers, rehospitalization data were re-analyzed by treatment status independent of experimental group.”
Groups received same cointerventions	Unclear risk	It is unclear whether the intervention participants received usual care (including comprehensive cardiac rehabilitation) plus intervention, or just intervention Methods: “The patients .... were randomised to either usual care (UC) or special intervention (SI).” Discussion: “our patients were already receiving considerable education and cognitive-behavioral intervention from merely being involved in cardiac rehabilitation.”

**Blumenthal 2016**

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> April 2010 to May 2014 (last event for medical event adjudication July 2015)</p> <p><b>Participants recruited (number of sites):</b> Duke University’s Center for Living and the University of North Carolina’s Wellness Center in Chapel Hill (2)</p> <p><b>Maximum follow-up:</b> 5.3 years.</p> <p><b>Follow-up schedule:</b> 1, 2, 3, 4, and 5 years.</p>
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Participants	<p><b>Inclusion criteria:</b> outpatients aged <math>\geq 35</math> years, with a documented history of CHD (ACS, stable angina, CABG, or PCI) who were eligible for cardiac rehabilitation in North Carolina, had capacity to provide informed consent and follow study procedures</p> <p><b>Exclusion criteria:</b> received a heart transplant or valvular repair surgery, LVEF <math>&lt; 30\%</math>, labile ECG changes prior to testing, current use of a pacemaker, resting blood pressure <math>&gt; 200/120</math> mmHg, left main disease <math>&gt; 50\%</math>, or were unable or unwilling to comply with assessment procedures or to be randomised into treatment groups</p> <p><b>Indication (% participants):</b> recent ACS, stable angina with angiographic evidence of coronary disease, and recent CABG or PCI: CABG (intervention: 25%; comparator: 13%), PCI (intervention: 38%; comparator: 31%), MI (intervention: 4%; comparator: 11%), MI + CABG (intervention: 3%; comparator: 3%), MI + PCI (intervention: 37%; comparator: 35%), angina (intervention: 4%; comparator: 8%)</p> <p><b>Psychopathology:</b> clinically elevated levels of depression, BDI-II <math>\geq 14</math> (34/151, 22.5%), clinically significant anxiety, STAI <math>\geq 40</math> (48/151, 32%), psychotropic medication at baseline (intervention: 34%; comparator: 35%)</p> <p><b>Number randomised:</b> total: 151; intervention: 76; comparator: 75.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: <math>61.8 \pm 10.8</math> years; comparator: <math>60.4 \pm 10.6</math> years</p> <p><b>Men:</b> total: NR; intervention: 59%; comparator: 68%.</p> <p><b>Ethnicity (% white):</b> total: NR; intervention: 76%; comparator: 68%.</p>
Interventions	<p><b>INTERVENTION:</b> stress management training, based on CBT. Initial sessions: establish rapport, promote group cohesion and social support, and accentuate the importance of stress as a risk factor for adverse cardiovascular events. Strategies involved: prioritising, time management, establishing personal values, and avoidance of stress-producing situations. Subsequent sessions: modifying responses to situations that could not be readily changed, and training in progressive muscle relaxation techniques and visual imagery to reduce stress. Emphasis was placed on the importance of cognitive appraisals in affecting stress responses, with recognition of irrational beliefs and cognitive distortions such as overgeneralisation, catastrophising, and all-or-nothing thinking. Later sessions: effective communication, assertiveness, anger management, and problem-solving strategies. Sessions involved brief lectures, group discussion, role playing, instruction in specific behavioural skills, and weekly 'homework' assignments</p> <p><b>Treatment targets:</b> reduce stress-linked demands (environmental, self-imposed), increase coping abilities, problem solving</p> <p><b>Components:</b> education, group support, CBT, relaxation training, anger management, and problem-solving strategies</p> <p><b>Treatment setting (number of sites):</b> Duke University's Center for Living and the University of North Carolina's Wellness Center in Chapel Hill (2)</p> <p><b>Modality (group size):</b> group (4-8 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1.5 hours;</li> <li>frequency/number of sessions: weekly/12;</li> <li>total duration: 12 weeks.</li> </ul> <p><b>Delivered by:</b> NR - although delivered as part of comprehensive cardiac rehabilitation programme</p> <p><b>Follow-up further reinforcement:</b> none.</p> <p><b>Cointerventions:</b> comprehensive cardiac rehabilitation programme (including struc-</p>

	tured exercise) <b>COMPARATOR:</b> comprehensive cardiac rehabilitation: aerobic exercise 3 times a week for 35 minutes at a level of 70-85% of their heart rate reserve as determined at the time of their initial exercise treadmill test, education about CHD, nutritional counselling based on American Heart Association guidelines, and 2 classes devoted to the role of stress in CHD <b>Cointerventions:</b> none.	
Outcomes	Total mortality. Non-fatal MI. Revascularisation (CABG). Hospitalisation for unstable angina.	
Source of funding	Grant HL093374 from the National Heart, Lung, and Blood Institute	
Conflicts of interest	Authors declared no conflict of interest.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	NR.
Allocation concealment (selection bias)	Unclear risk	NR.
Blinding of outcome assessment (detection bias)	Low risk	“Medical records were reviewed and events, categorised based on ACC/AHA [American College of Cardiology/American Heart Association] criteria, 21 were adjudicated by a physician assistant and a study cardiologist blinded to treatment condition.”
Incomplete outcome data (attrition bias) All outcomes	Low risk	All cardiac events data were collected from routine records with data available from all 151 participants
Selective reporting (reporting bias)	Low risk	All clinical events described in methods section reported in <a href="#">Table 4</a> .
Groups balanced at baseline	Low risk	“The treatment groups were similar on background and demographic characteristics...”
Intention-to-treat analysis	Low risk	“Treatment effects were analyzed following the intention-to-treat (ITT) principle.”



Groups received same cointerventions	Unclear risk	Both groups received comprehensive cardiac rehabilitation.
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**Brown 1993**

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> cardiac rehabilitation centres (5), adverts.</p> <p><b>Maximum follow-up:</b> 15 months.</p> <p><b>Follow-up schedule:</b> 3, 9, and 15 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged 43-75 years; MI or bypass surgery (or both) occurred 4-24 months before study; prognosis of no worse than 3.3 based on NYHA; stable cardiac status with no medical contraindications to increase physical activity; onset of depression or anxiety (or both) associated with the MI or bypass surgery based on the SADS-C; score &gt; 13 on BDI or &gt; 70 on the SCL-90-R indicating clinically significant levels of depression and distress; spouses, friends, or relatives who were willing to participate in the treatment</p> <p><b>Exclusion criteria:</b> pre-existing psychiatric disorders.</p> <p><b>Indication (% participants):</b> MI only (30%), bypass only (38%), MI + bypass (32%).</p> <p><b>Psychopathology:</b> eligibility criteria psychopathology (100%).</p> <p><b>Number randomised:</b> total: 54; intervention: NR; comparator: NR.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 60.7 (SD NR) years; intervention: 63.6 <math>\pm</math> 7.4 years; comparator: 57.7 <math>\pm</math> 7.8 years</p> <p><b>Men:</b> total: 73%; intervention: 55%; comparator: 90%.</p> <p><b>Ethnicity (% white):</b> total: 100%.</p>
Interventions	<p><b>INTERVENTION:</b> individuals were shown how to increase the rate and intensity of their adaptive behaviours, including pleasant activities, relaxation, cognitive restructuring, assertion/anger management, and time management. In each session, the therapist provided a rationale for an adaptive behaviour, gave specific instructions in performing the behaviour, and demonstrated the behaviour. After the partner gave the participant specific, primarily positive feedback and reinforcement. The partner practised ignoring the participant's maladaptive behaviours. Finally, the therapist, participant, and partner collaborated and planned ways the participant and partner would practise the skills and monitor progress</p> <p><b>Treatment targets:</b> stress management.</p> <p><b>Components:</b> relaxation, cognitive restructuring, assertion anger management, and time management. Partners were also trained to give positive feedback and reinforcement</p> <p><b>Treatment setting (number of sites):</b> hospital (5).</p> <p><b>Modality (group size):</b> group (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1 hour;</li> <li>frequency/number of sessions: weekly/12;</li> <li>total duration: 12 contact hours over 12 weeks.</li> </ul> <p><b>Delivered by:</b> clinical psychologist and psychiatrist.</p> <p><b>Follow-up further reinforcement:</b> NR.</p>

	<b>Cointerventions:</b> NR. <b>COMPARATOR:</b> control group had time with therapists where they received non-specific treatment effects of encouragement and reassurance, excluding key behaviour therapies <b>Cointerventions:</b> NR.	
Outcomes	Depression (BDI, SADS-C). Psychological distress and depression (SCL-90-R Global Severity Index score)	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	NR.
Allocation concealment (selection bias)	Unclear risk	NR.
Blinding of outcome assessment (detection bias)	Unclear risk	NR.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	NR.
Selective reporting (reporting bias)	Unclear risk	NR.
Groups balanced at baseline	High risk	Control participants were significantly younger than those in the intervention group
Intention-to-treat analysis	Unclear risk	NR.
Groups received same cointerventions	Low risk	Control group had time with therapists where they received non-specific treatment effects of encouragement and reassurance, but key behaviour therapies were not provided

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Sweden.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (14).</p> <p><b>Maximum follow-up:</b> 6.5 years.</p> <p><b>Follow-up schedule:</b> 6.5 years.</p>
Participants	<p><b>Inclusion criteria:</b> CABG 3-12 months prior to recruitment, non-smokers.</p> <p><b>Exclusion criteria:</b> diabetes mellitus, other somatic or psychiatric disease or alcoholism, and non-Swedish speakers</p> <p><b>Indication (% participants):</b> CABG (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 261; intervention: 128; comparator: 133.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 57.5 (SD NR) years; intervention: NR; comparator: NR</p> <p><b>Men:</b> total: 86%; intervention: NR; comparator: NR.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> initial treatment (6 sessions) focused on education about CHD, surgical issues, risk factors and risk behaviours, psychological factors that influence well-being and Type A behaviour. From the first session, participants were given homework assignments related to observation of health behaviours. The remaining session focused on modifying Type A prone behaviours: developing and applying new reactions and behaviours that entailed less impatience, irritation, hostility, depression, and distress</p> <p><b>Treatment targets:</b> risk education, disease adjustment, and coronary prone behaviours (Type A behaviour, depressive reactions, anxiety)</p> <p><b>Components:</b> risk information, guidance on behaviour change, self-awareness/monitoring, relaxation, homework</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (5-9 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 3 hours;</li> <li>frequency/number of sessions: every third week/17;</li> <li>total duration: 51 contact hours over 1 year.</li> </ul> <p><b>Delivered by:</b> cardiologist and nutritionist (1 session) and clinical psychologist (remainder of sessions)</p> <p><b>Follow-up further reinforcement:</b> 5 or 6 booster sessions in years 2 and 3.</p> <p><b>Cointerventions:</b> access to rehabilitation programmes that were part of usual care</p> <p><b>COMPARATOR:</b> usual care, including access to rehabilitation programmes that were regularly offered by participating hospitals</p> <p><b>Cointerventions:</b> NR.</p>
Outcomes	<p>Total mortality.</p> <p>Cardiac mortality.</p> <p>Non-fatal MI.</p> <p>Revascularisation (CABG (reoperation) and PTCA).</p> <p>Self-reported Type A behaviour.</p>
Source of funding	NR.

**Burell 1996a** (Continued)

Conflicts of interest	NR.	
Notes		
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Stated participants were randomly assigned.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to judge, attrition appeared to be zero
Selective reporting (reporting bias)	Unclear risk	Method did not fully specify the measures used.
Groups balanced at baseline	High risk	Control participants were significantly younger than those in the intervention group
Intention-to-treat analysis	Unclear risk	Intention-to-treat analysis was not described, and no n values were provided in <a href="#">Table 1</a> .
Groups received same cointerventions	Low risk	“Both experimental and control patients had access to rehabilitation programmes that were regularly offered by their hospitals.”

**Burgess 1987**

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> NR (study conducted 1981-1984).</p> <p><b>Participants recruited (number of sites):</b> hospital (11).</p> <p><b>Maximum follow-up:</b> 13 months.</p> <p><b>Follow-up schedule:</b> 3 and 13 months.</p>
Participants	<p><b>Inclusion criteria:</b> men and women, aged 18-62 years, employed <math>\geq 20</math> hours per week outside the home, and who met <math>\geq 2</math> of the following criteria for MI: typical symptoms of MI (e.g. prolonged chest discomfort, dyspnoea, arm pain, and diaphoresis); ECG evidence of MI; and diagnostic elevations of serum enzymes consistent with myocardial</p>

	<p>necrosis</p> <p><b>Exclusion criteria:</b> cardiac complications and other comorbid conditions considered to mitigate against re-employment</p> <p><b>Indication (% participants):</b> AMI (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 180; intervention: 89; comparator: 91.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 50.9 <math>\pm</math> 7.4 years; intervention: 51.6 <math>\pm</math> 7.1 years; comparator: 50.2 <math>\pm</math> 7.7 years</p> <p><b>Men:</b> total: 86%; intervention: 85%; comparator: 86%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> programme had 3 aims: to limit participant psychological distress, using a cognitive-behavioural intervention model; to minimise social network strain by providing guidance and moral support to participants and to a key member of each participant's primary social network; and to facilitate job re-entry</p> <p>Intervention strategies based on the cognitive behavioural model focused particular attention on how the nurses could alter assumptions and beliefs about MI and recovery. Participant, family members, and key people at the workplace were all assessed about their beliefs regarding the MI and related events. Information about the participant's postinfarction experiences was most useful in enhancing relaxation and reframing assumptions</p> <p><b>Treatment targets:</b> disease adjustment, anxiety, and depression.</p> <p><b>Components:</b> cognitive challenge/restructuring and social support, client-led discussion</p> <p><b>Treatment setting (number of sites):</b> participant home (NR), telephone.</p> <p><b>Modality (group size):</b> individual.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: NR;</li> <li>frequency/number of sessions: NR (mean number of contacts per participant 6.32);</li> <li>total duration: insufficient information to calculate contact hours, over 3 months.</li> </ul> <p><b>Delivered by:</b> team of specially trained, masters-prepared nurse clinicians</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> usual medical care, including access to comprehensive cardiac rehabilitation</p> <p><b>COMPARATOR:</b> usual hospital medical care, including access to comprehensive cardiac rehabilitation, although this was limited in scope as most services were only recently developed in the 11 participating hospitals</p> <p><b>Cointerventions:</b> NR.</p>
Outcomes	<p>Total mortality.</p> <p>Anxiety (Taylor 1953).</p> <p>Depression (ZDS).</p> <p>Return to work.</p>
Source of funding	The Robert Wood Johnson Foundation, Princeton, New Jersey, USA
Conflicts of interest	NR.
Notes	

**Burgess 1987** (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Randomisation was conducted by telephone from the study's central office; stratified by sex. Research assistant opened sealed envelopes
Blinding of outcome assessment (detection bias)	Unclear risk	Insufficient detail provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not described.
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	"The absence of statistically significant differences between treatment groups on any key variables measured at the baseline attests to the effectiveness of the randomisation procedure."
Intention-to-treat analysis	Low risk	No intention-to-treat analysis was described, but <a href="#">Table 1</a> suggested that participants were analysed according to randomisation group
Groups received same cointerventions	Unclear risk	Comparator group received "conventional hospital rehabilitation (usual care)" which was not described

**Claesson 2005**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Sweden.</p> <p><b>Dates participants recruited:</b> 1997-2001.</p> <p><b>Participants recruited (number of sites):</b> hospital discharge registers (NR).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 1 year.</p>
Participants	<p><b>Inclusion criteria:</b> woman aged &lt; 80 years with first or recurrent AMI, or who had undergone coronary angioplasty or CABG surgery, or had angina pectoris with CAD confirmed by angiography and treated non-invasively and given informed consent</p>

	<p><b>Exclusion criteria:</b> AMI, coronary angioplasty, or CABG surgery within the last 4 months; unstable CAD with a planned invasive investigation or treatment; any diseases that could interfere with trial participation or therapy (e.g. malignancy or psychiatric disease (depression excepted)); non-Swedish speaking; other apparent obstacles making it difficult to participate in regular group activities (e.g. alcohol or drug abuse); and participation in another treatment study</p> <p><b>Indication (% participants):</b> AMI (70%), CABG (34%), PCI (40%), some participants <math>\geq 1</math> conditions at baseline</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 198; intervention: 101; comparator: 97.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 61.0 (SD NR) years; intervention: <math>59.0 \pm 2.0</math> years; comparator: <math>62.0 \pm 2.0</math> years</p> <p><b>Men:</b> total: 0%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> structured programme similar to CBT, including 5 key components: education, self-monitoring, skills training, cognitive restructuring, and spiritual development</p> <p><b>Treatment targets:</b> risk reduction, stress, anxiety, depression.</p> <p><b>Components:</b> coronary risk information, self-monitoring/awareness, relaxation, cognitive challenge/restructuring; also some guidance on behaviour change</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (5-9 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 2 hours;</li> <li>frequency/number of sessions: weekly/10 (sessions 1-10) and then over 42 weeks/10;</li> <li>total duration: 40 contact hours over 1 year.</li> </ul> <p><b>Delivered by:</b> physiotherapist with specialist training.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> all participants received general lifestyle advice on diet, physical training, and smoking cessation prior to randomisation, and usual medical care postrandomisation</p> <p><b>COMPARATOR:</b> usual medical care, including general lifestyle advice on diet, physical training, smoking cessation, and an introduction to stress management/relaxation training prior to randomisation. Postrandomisation, all participants received conventional care and follow-up, including outpatient visits to cardiologists and cardiology nurses</p> <p><b>Cointerventions:</b> NR.</p>
Outcomes	<p>Total mortality.</p> <p>Non-fatal MI.</p> <p>Revascularisation (<i>reported Claesson 2005, note slightly different samples reported</i>).</p> <p>Depression (Comprehensive Psychopathological Rating Scale Self-Affective)</p> <p>Quality of life (3 rating scales).</p> <p>Self-rated stress behaviour and reactions scale (The Everyday Life Stress scale)</p> <p>Vital exhaustion (Maastricht Questionnaire).</p>
Source of funding	<p>The Vardal Foundation, the Swedish Medical Research Council (grant no. K2001-27X-13457-02B), the Swedish Council for Social Research, the Swedish Heart and Lung</p>

	Foundation, foundations by the Faculty of Medicine, and Odontology at the Umea University, the Norrland Heart Foundation, the Vasterbotten County Council, the Arnerska Research Foundation, JC Kempe’s and Golje’s foundations	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Randomisation was stratified by geographical areas, but no mention was made of the method used to generate the sequence
Allocation concealment (selection bias)	Low risk	“Randomisation was by sealed envelopes.”
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	For continuous outcomes, intention-to-treat was not performed because follow-up data were not available for 27 women who withdrew; however, dropouts and reasons were provided
Selective reporting (reporting bias)	Low risk	Analyses provided for all outcomes mentioned in methods (and protocol). Data only provided as figures, and not in tabular/numerical form
Groups balanced at baseline	Low risk	“There was significantly younger age in the intervention group, as compared with the UC [usual care] group.” But most ANCOVA analysis adjusted for baseline differences in age between groups
Intention-to-treat analysis	High risk	“Intention-to-treat analyses were not suitable as there were no follow-up data (psychosocial questionnaires, biochemical or biomedical measures) in the women who withdrew from the study.”
Groups received same cointerventions	Low risk	“Before randomization, all participants in the present trial (also those in the control group)...received general lifestyle advice on diet, physical training and smoking cessation...All women received conventional



	care and follow-up for women with IHD [ischaemic heart disease].”
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## Davidson 2010

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> 1 January 2005 to 29 February 2008.</p> <p><b>Participants recruited (number of sites):</b> hospital (5).</p> <p><b>Maximum follow-up:</b> 15 months.</p> <p><b>Follow-up schedule:</b> 3, 5, 7, 9, and 18 months (note: randomisation at 3 months post-baseline)</p>
Participants	<p><b>Inclusion criteria:</b> diagnosis of ACS and with persistent depressive symptoms (BDI score <math>\geq 10</math> on assessments within 1 week of hospitalisation for ACS and 3 months later)</p> <p><b>Exclusion criteria:</b> alcohol or drug dependency, dementia, current or past psychosis or bipolar disorder, terminal illness, unavailability for follow-up, BDI score <math>\geq 45</math>, or suicidality</p> <p><b>Indication (% participants):</b> ACS (100%) - unstable angina (intervention: 73%; comparator: 78%), non-ST-STEMI (intervention 16%; comparator: 12%), ST-segment elevation MI (intervention: 10%; comparator: 10%)</p> <p><b>Psychopathology:</b> persistent depressive symptoms (100%).</p> <p><b>Number randomised:</b> total: 157; intervention: 80; comparator: 77.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: 59.3 <math>\pm</math> 10.6 years; comparator: 61.1 <math>\pm</math> 10.6 years</p> <p><b>Men:</b> total: NR; intervention: 46; comparator: 47.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> included: an enhanced care approach; participant choice of psychotherapy or pharmacotherapy (or both); problem-solving therapy; a stepped-care approach in which symptom severity was reviewed every 8 weeks and treatment was augmented according to predetermined decision rules; and a standardised instrument used to track depressive symptoms</p> <p><b>Treatment targets:</b> depressive symptoms.</p> <p><b>Components:</b> psychotherapy and pharmacotherapy.</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> NR, but presumed individual (“in person or by telephone”).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 30-45 minutes;</li> <li>frequency/number of sessions: weekly/visit frequency was decreased/increased according to individual participant’s progress and preferences;</li> <li>total duration: insufficient information to calculate contact hours, over 6 months.</li> </ul> <p><b>Delivered by:</b> clinical nurse specialist, psychologist, social worker, psychiatrist, or a combination of these</p> <p><b>Follow-up further reinforcement:</b> at the end of the trial, participants were provided with 6 further months of medication if they could not afford it but were referred to their usual care provider for follow-up</p> <p><b>Cointerventions:</b> none described. Pharmacotherapy (antidepressant medication) offered</p>

	as part of preference trial. Intervention participants choosing pharmacotherapy were initially seen at 1- to 2-week intervals for dose titration and thereafter every 3-5 weeks as needed for the remainder of the 6-month trial period <b>COMPARATOR:</b> usual care, as defined by the participant’s treating physicians <b>Cointerventions:</b> NR.	
Outcomes	Total mortality. Non-fatal MI (as part of a composite indicator only). Anxiety (HADS-A). Depression (BDI).	
Source of funding	The National Heart, Lung, and Blood Institute and the National Center for Research Resources, a component of the National Institutes of Health and National Institutes for Health Roadmap for Medical Research	
Conflicts of interest	NR.	
Notes	Anxiety outcome data reported in Kronish 2012.	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	“At each site, eligible patients were randomised on a 1:1 basis within randomly ordered blocks of 4 or 6 patients according to a table of assignments prepared in advance by the trial statistician (J.E.S.).”
Allocation concealment (selection bias)	Low risk	“Using a Web-based programme, project coordinators specified the strata, initials, and study identification number of the person to be randomised, and the programme issued the group assignment.”
Blinding of outcome assessment (detection bias)	Low risk	“Interviewers and those collecting medical outcome data were blinded to intervention assignment.”
Incomplete outcome data (attrition bias) All outcomes	High risk	Lost to follow-up: intervention: 20/80 (25%); control: 6/77 (8%)
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported for all time points
Groups balanced at baseline	Low risk	“Patients randomised to the intervention and usual care groups were similar on all baseline variables.”

Intention-to-treat analysis	Low risk	Results were reported as “intention-to-treat estimates.”
Groups received same cointerventions	Low risk	No cointerventions were given to either group.

## Elderen-van-Kemenade 1994

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Netherlands.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 2 months and 1 year.</p>
Participants	<p><b>Inclusion criteria:</b> admitted to hospital with an AMI.</p> <p><b>Exclusion criteria:</b> aged &gt; 70 years.</p> <p><b>Indication (% participants):</b> AMI (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 60; intervention: 30; comparator: 30.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 57 (SD NR) years; intervention: <math>55.6 \pm 7.4</math> years; comparator: <math>58.8 \pm 8.0</math> years</p> <p><b>Men:</b> total: 82%; intervention: 77%; comparator: 87%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> 2 individual counselling sessions and 2 group health education sessions focusing on medication, healthy habits, anxiety, and depression</p> <p><b>Treatment targets:</b> risk education and behaviour change; also attention paid to disease adjustment, anxiety, and depression</p> <p><b>Components:</b> risk information, guidance on behaviour change, self-awareness/monitoring, client-led discussion; some emotional support</p> <p><b>Treatment setting (number of sites):</b> hospital (1).</p> <p><b>Modality (group size):</b> individual counselling + 2 group sessions (NR) while in hospital, and 6-weekly telephone calls upon hospital discharge</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 90 minutes;</li> <li>frequency/number of sessions: 2 x in-hospital counselling sessions + weekly follow-up calls/8 (mean);</li> <li>total duration: insufficient information to calculate contact time or duration.</li> </ul> <p><b>Delivered by:</b> psychologist.</p> <p><b>Follow-up further reinforcement:</b> weekly telephone calls were made to participants for a period of 6 weeks after discharge, when participants were given the opportunity to talk about their psychosocial problems</p> <p><b>Cointerventions:</b> health education sessions. The topics of these were 'a new start after the myocardial infarction' including advice on physical exercise and healthy eating and risk factors</p> <p><b>COMPARATOR:</b> usual medical care (including physical rehabilitation), although systematic health education was not a standard component</p>

	<i>Cointerventions:</i> NR.	
Outcomes	Anxiety (Dutch version: STAI). Vital exhaustion and depression (Maastricht Questionnaire for Vital Exhaustion and Depression)	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Alternate allocation - in a 2-week period, all participants admitted to the hospital for an MI were invited to participate and were assigned to the experimental condition; in a subsequent 2-week period, all participants admitted to the hospital for an MI were assigned to the control condition
Allocation concealment (selection bias)	High risk	Quasi-randomisation. See above.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	High risk	Dropouts in each group accounted for, but results not based on intention-to-treat analyses
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	“Chi-square analyses performed on the data gathered in the pre-test (see Table 1) revealed no statistically significant differences between patients in the experimental and control conditions in demographic characteristics.”
Intention-to-treat analysis	High risk	Participants who dropped out were not included in the analyses
Groups received same cointerventions	High risk	Intervention contained an education component which was not part of standard care

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> October 1996 to October 1999.</p> <p><b>Participants recruited (number of sites):</b> hospital (73) affiliated to clinical centres (8).</p> <p><b>Maximum follow-up:</b> 4.5 years.</p> <p><b>Follow-up schedule:</b> 3 (telephone), 6 (visit), 9 (telephone), 12 (telephone), and 18 (visit) months, then every 6 months thereafter, alternating telephone and visits, until April 2001</p>
Participants	<p><b>Inclusion criteria:</b> men and women recruited during a hospitalisation for a verified AMI with either symptoms compatible with AMI or characteristic evolutionary ECG ST-T changes or new Q waves, reporting depressive symptoms or a lack of social support (or both)</p> <p><b>Exclusion criteria:</b> comorbidity, logistical barriers, and lack of informed consent</p> <p><b>Indication (% participants):</b> AMI (100%).</p> <p><b>Psychopathology:</b> eligibility criteria depression only (39%), low social support only (26%), depressed and low social support (35%)</p> <p><b>Number randomised:</b> total: 2481; intervention: 1238; comparator: 1243.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 61 (SD NR) years; intervention: 61 <math>\pm</math> 12.5 years; comparator: 61 <math>\pm</math> 12.6 years</p> <p><b>Men:</b> total: 56%; intervention: 57%; comparator: 56%.</p> <p><b>Ethnicity (% white):</b> total: 66%; intervention: 67%; comparator: 66%.</p>
Interventions	<p><b>INTERVENTION:</b> depressed people received CBT, focusing on behavioural activation, active problem solving, and efforts to modify depressogenic automatic thoughts or self-talk. People with severe or unremitting depression received pharmacotherapy with a selective serotonin reuptake inhibitor if unresponsive to psychotherapy. People with low social support received a similarly targeted treatment that focused on social skill deficits and automatic thoughts or self-talk that interfered with social engagement. The primary mode of treatment was individual therapy, supplemented with group therapy where feasible</p> <p><b>Treatment targets:</b> depression (and low social support), and secondary goals around behaviour change, disease adjustment, stress, anxiety, Type A behaviours, and exhaustion</p> <p><b>Components:</b> guidance on behaviour change, cognitive challenge/restructuring, homework. Also some self-awareness/monitoring, relaxation, client-led discussion, emotional support</p> <p><b>Treatment setting (number of sites):</b> individual sessions in the participant's home or counsellor's office (NR); group sessions NR (NR)</p> <p><b>Modality (group size):</b> individual and group (minimum 3 participants) where deemed feasible</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1 hour (individual sessions), 2 hours (group sessions);</li> <li>frequency/number of sessions: maximum of 6 months (individual sessions) or 9 months (group sessions). Median number of individual sessions 1. 31% received 12 group sessions;</li> <li>total duration: 18.44 contact hours, total duration NR.</li> </ul> <p><b>Delivered by:</b> therapist trained by study psychologists.</p> <p><b>Follow-up further reinforcement:</b> none.</p> <p><b>Cointerventions:</b> participants in the intervention group meeting criterion for depression</p>

	<p>were offered antidepressant pharmacotherapy (sertraline hydrochloride) donated by the manufacturer, and provided without charge for up to 12 months. Alternative medications were offered where clinically appropriate and participants may have been referred to cardiac rehabilitation or support groups by their physician as part of usual care</p> <p><b>COMPARATOR:</b> referral to cardiac rehabilitation/support groups by participant’s own physician was considered to be usual care. Pharmacotherapy was allowed for control group participants, but participants had to seek diagnosis and treatment from their own physician</p> <p><b>Cointerventions:</b> NR.</p>	
Outcomes	<p>Total mortality.</p> <p>Cardiac mortality.</p> <p>Non-fatal MI.</p> <p>Depression (BDI, HAM-D).</p> <p>HRQoL (SF-12 Physical and Mental Component Scores).</p> <p>Life satisfaction (Ladder of Life Scale).</p>	
Source of funding	<p>The National Heart, Lung, and Blood Institute, National Institute of Health, Bethesda, Maryland. Pfizer provided sertraline (Zoloft) for the study</p>	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Stratified by clinical centre and used a permuted block algorithm
Allocation concealment (selection bias)	Low risk	Study coordinators obtained treatment allocation using automated telephone randomisation system maintained at the <a href="#">ENRICHD Investigators 2000</a> Coordinating Center.
Blinding of outcome assessment (detection bias)	Low risk	All staff who collected, verified, or classified end point data or follow-up assessments were masked as much as possible
Incomplete outcome data (attrition bias) All outcomes	Low risk	“All treatment group comparisons were based on the intention-to-treat principle that includes all randomised patients as randomised.”
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section

## ENRICHD Investigators 2000 (Continued)

Groups balanced at baseline	Low risk	“Treatment groups were balanced on key baseline characteristics and prognostic factors.”
Intention-to-treat analysis	Low risk	“All treatment group comparisons were based on the intention-to-treat principles.”
Groups received same cointerventions	Low risk	“Both groups receive usual care while in the hospital and written materials providing education on risk factors, based on the AHA [American Heart Association] Active Partnership@ Program.”

## Freedland 2009

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> December 2001 to August 2005.</p> <p><b>Participants recruited (number of sites):</b> hospital (3).</p> <p><b>Maximum follow-up:</b> 9 months.</p> <p><b>Follow-up schedule:</b> 6 and 9 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged <math>\geq 21</math> years, had undergone CABG surgery within the past year; current antidepressant medication was not an exclusion criterion, as long as a therapeutic dose had been taken for at least 6 weeks; BDI score <math>\geq 10</math> and who met DSM-IV criteria for a current major or minor depressive episode, as determined by the DISH</p> <p><b>Exclusion criteria:</b> severe psychiatric comorbidities, such as schizophrenia or bipolar disorder, active alcoholism or substance abuse, severe cognitive impairment, non-cardiac illnesses with a poor 1-year prognosis, being too medically ill or living too far away to participate, being unable to communicate in English, or for receiving ongoing psychotherapeutic services</p> <p><b>Indication (% participants):</b> CABG (100%).</p> <p><b>Psychopathology:</b> minor or major depression, <math>\geq 10</math> on BDI, met DSM-IV criteria for a current major or minor depressive episode DISH (100%)</p> <p><b>Number randomised:</b> total: 123; intervention 1 (CBT): 41; intervention 2 (SSM): 42; comparator: 40</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention 1 (CBT): <math>62.0 \pm 11.0</math> years; intervention 2 (SSM): <math>59.0 \pm 10.0</math> years; comparator: <math>61.0 \pm 9.0</math> years</p> <p><b>Men:</b> total: NR; intervention 1 (CBT): 44%; intervention 2 (SSM): 50%; comparator: 57%</p> <p><b>Ethnicity (% white):</b> total: NR; intervention 1 (CBT): 88%; intervention 2 (SSM): 67%; comparator: 90%</p>
Interventions	<p><b>INTERVENTION 1 CBT:</b> target problem identification, problem solving, behavioural activation, cognitive techniques (challenging distressing automatic thoughts and changing dysfunctional attitudes), consolidation of the self-therapy and relapse-prevention skills. Brief telephone contacts between treatment sessions as needed. Each case reviewed</p>

	<p>in a weekly supervision meeting with 1 of the investigators. Earlier sessions usually emphasised</p> <p><b>INTERVENTION 2 SSM:</b> a supportive therapeutic relationship setting, to improve participant's coping skills for stressful life events and daily stressors. Discussion of recent stressful experiences and impact on mood, progressive relaxation training and other techniques (controlled breathing and relaxing imagery). Participants asked to practise them daily and maintain a practice log. As proficiency in relaxation skills improved, they were asked to apply them to stressful or distressing situations in daily life. Weekly sessions (twice weekly permitted occasionally)</p> <p><b>Treatment targets:</b> CBT: distressing automatic thoughts, dysfunctional attitudes, re-engaging with routine activities; SSM: participant's ability to cope with stressful life events and daily stressors</p> <p><b>Components:</b> CBT: problem solving, behavioural activation, cognitive techniques; SSM: coping skills, relaxation training</p> <p><b>Treatment setting (number of sites):</b> outpatient research clinic (1).</p> <p><b>Modality (group size):</b> individual.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>length of session: 50-60 minutes of face-to-face sessions, supportive telephone calls when needed;</li><li>frequency/number of sessions: 1-2 times weekly/12-16;</li><li>total duration: insufficient information to calculate contact hours, over 12 weeks.</li></ul> <p><b>Delivered by:</b> CBT: 1 of 3 therapists (2 clinical psychologists and 1 clinical social worker) with training and experience in CBT; SSM: 1 of 3 therapists (2 clinical social workers and 1 counselling psychologist) with training and experience in counselling and stress management interventions</p> <p><b>Follow-up further reinforcement:</b> brief telephone contacts between sessions as needed, and 2 weekly sessions were allowed when needed</p> <p><b>Cointerventions:</b> interventions were provided in addition to, not as a replacement for, any antidepressant medications that the participants may have been receiving from their physicians</p> <p><b>COMPARATOR:</b> usual care which may have included antidepressant medications that the participants may have been receiving from their physicians</p> <p><b>Cointerventions:</b> none.</p>	
Outcomes	Anxiety (Beck Anxiety Inventory). Depression (HAM-D, BDI). HRQoL (SF-36 Physical and Mental component scores). Perceived stress scale (Cohen Perceived Stress scale). Beck Hopelessness Scale.	
Source of funding	National Institute of Mental Health, USA.	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
Bias	Authors' judgement	Support for judgement



**Freedland 2009** (Continued)

Random sequence generation (selection bias)	Low risk	"We used a SAS programme (SAS Institute, Cary, North Carolina) to generate a random allocation sequence with block sizes of 3 and 6."
Allocation concealment (selection bias)	Low risk	"Group assignments were concealed in sealed envelopes and revealed to the study coordinator immediately after the participant completed all of the baseline assessments."
Blinding of outcome assessment (detection bias)	Low risk	"The outcome assessors were masked to the participants' group assignments."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up at 9 months: CBT: 1/40 (3%); SSM: 7/42 (17%); usual care: 4/40 (10%)
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	"The proportion of African American participants randomly assigned to the SSM arm was higher than expected ( $P=.01$ ). There were no other significant differences in the characteristics of the groups."
Intention-to-treat analysis	Low risk	"The outcome analyses conformed to the intention-to-treat principle."
Groups received same cointerventions	Low risk	"interventions were provided in addition to, not as a replacement for, any antidepressant medications that the participants may have been receiving from their physicians."

**Friedman 1982**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> media adverts, invitations from cardiologists, corporate and union executives (NR)</p> <p><b>Maximum follow-up:</b> 5 years.</p> <p><b>Follow-up schedule:</b> 1, 2, 3, 4, and 5 years.</p>
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Participants	<p><b>Inclusion criteria:</b> experienced with their first or last documented AMI <math>\geq 6</math> months earlier; had either never smoked or had quit smoking cigarettes, cigars, or pipes for 6 months or longer; and had never been treated for or exhibited signs of diabetes</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> MI within 6 months (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 884; intervention (Type A behavioural counselling): 614; comparator (cardiology counselling): 270</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: 53.1 <math>\pm</math> 6.7 years; comparator: 53.4 <math>\pm</math> 6.4 years</p> <p><b>Men:</b> total: NR; intervention: 90%; comparator: 95%.</p> <p><b>Ethnicity (% white):</b> total: 98%; intervention: NR; comparator: NR.</p>
Interventions	<p><b>INTERVENTION:</b> Type A behavioural counselling including: relaxation training (progressive muscle relaxation and mental relaxation) and behavioural learning (recognition and modification of exaggerated arousal reactions, instruction in self-observation and self-assessment techniques, restructuring of environment, and cognitive-affective learning)</p> <p><b>Treatment targets:</b> behaviour change, cardiac risk reduction, disease adjustment, stress, Type A behaviours</p> <p><b>Components:</b> guidance on behaviour change, risk factor management, self-awareness/monitoring, relaxation, cognitive challenge/restructuring, homework</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (10 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: NR;</li> <li>frequency/number of sessions: weekly for 2 months/NR, every 2 weeks for 2 months/NR, monthly for remainder of study/NR. Cardiologist visited once every 3 months;</li> <li>total duration: insufficient information to calculate contact hours, total duration NR.</li> </ul> <p>Section 2 groups initially met with their counsellors weekly for 2 months, every 2 weeks for 2 months, and were scheduled to meet monthly for the remainder of the study. They were visited every 3 months by a cardiologist who discussed specific cardiovascular problems possibly confronting participants</p> <p><b>Delivered by:</b> psychiatrists, clinical/counselling psychologists, and 2 cardiologists</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> cardiological counselling on risk factor reduction delivered by a cardiologist and usual medical care</p> <p><b>COMPARATOR:</b> cardiology counselling ('Section 1') delivered by cardiologists in a group setting (12 participants per group). Groups met every 2 weeks for 3 months, monthly for 3 months, and twice monthly for the remainder of the study, and visited every 3 months by a psychiatrist or psychologist. Participants received risk factor counselling aimed at enhancing compliance with the dietary, exercise, and drug regimen prescribed for them by their personal physicians. Participants were informed of all advances in the diagnosis and treatment of CHD. Usual medical care was also available</p> <p><b>Cointerventions:</b> NR.</p>

Outcomes	Cardiac mortality. Non-fatal MI. Type A behaviour (based on clinical checklist/observations).	
Source of funding	National Heart, Lung, and Blood Institute, Bank of America, Standard Oil of California, The Kaiser Hospital Foundation, The Zellerbach Family Foundation and the Mary Potishman Lard Foundation	
Conflicts of interest	NR.	
Notes		
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomisation, using a table of random numbers, was conducted in a ratio of 2:1 to intervention and control group
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Type A behaviour was assessed by 1 interviewer blind to treatment status
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Analyses were conducted on an intention-to-treat basis.”
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	Table 1 showed that baseline characteristics and prognostic factors were similar for the intervention and comparator group
Intention-to-treat analysis	High risk	Data from dropouts were not included in the analyses of year 1 data (Table 5) by group allocation, but presented separately as a 'drop-out' group (including both Section 1 and 2 participants)
Groups received same cointerventions	Low risk	The only difference between intervention and comparator groups is the addition of Type A behaviour counselling. Both groups received risk factor education counselling and usual medical care

Methods	<i>Design:</i> RCT. <i>Country:</i> UK. <i>Dates participants recruited:</i> NR. <i>Participants recruited (number of sites):</i> general practices (30). <i>Maximum follow-up:</i> 6 months. <i>Follow-up schedule:</i> 6 months.	
Participants	<i>Inclusion criteria:</i> men aged < 70 years who were currently being prescribed nitrates (as tablets, sprays, or patches) or nifedipine (calcium antagonist) for angina <i>Exclusion criteria:</i> NR. <i>Indication (% participants):</i> angina (100%). <i>Psychopathology:</i> NR. <i>Number randomised:</i> total: 452; intervention: 227; comparator: 225. <i>Age (mean ± SD):</i> total: NR; intervention: NR; comparator: NR. <i>Men:</i> total: 100%. <i>Ethnicity (% white):</i> NR.	
Interventions	<b>INTERVENTION:</b> instruction in stress management was given in 3 group sessions each of about 1 hour. Stress management included identifying stress triggers, stressful thoughts and feelings, and relaxation techniques. The cognitive coping strategies of 'self-talk' and cognitive challenge were taught. Participants were also asked to practise relaxation and read a course 'manual' at home <i>Treatment targets:</i> stress reduction. <i>Components:</i> relaxation and homework assignments, plus some self-monitoring/awareness and client-led discussion <i>Treatment setting (number of sites):</i> clinic (NR). <i>Modality (group size):</i> group (3-8 participants). <i>Dose:</i> <ul style="list-style-type: none"><li>length of session: 1 hour + homework;</li><li>frequency/number of sessions: weeks 1, 4, and 10/3;</li><li>total duration: insufficient information to calculate contact hours, over 10 weeks.</li></ul> <i>Delivered by:</i> psychologist. <i>Follow-up further reinforcement:</i> NR. <i>Cointerventions:</i> NR. <b>COMPARATOR:</b> usual medical care. <i>Cointerventions:</i> NR.	
Outcomes	Stress (Derogatis Stress Profile).	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

**Gallacher 1997** (Continued)

Random sequence generation (selection bias)	Unclear risk	Stated that the participants were randomly allocated in a factorial design which included 8 groups (of which 4 were reported in this study)
Allocation concealment (selection bias)	Unclear risk	"Randomisation was achieved with 8 envelopes."
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"All analyses followed the 'intention-to-treat principle as far as the follow-up data allowed."
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	"Comparison of cardiovascular risk factors at baseline, using 't' test and Chi Square Test as appropriate, showed no differences between the two groups."
Intention-to-treat analysis	Low risk	"All analyses followed the 'intention-to-treat' principle as far as the follow-up data allowed."
Groups received same cointerventions	Low risk	No cointerventions were reported.

**Gulliksson 2011**

Methods	<p><b>Design:</b> single-centre, parallel groups RCT.</p> <p><b>Country:</b> Sweden.</p> <p><b>Dates participants recruited:</b> 1 May 1996 to 31 August 2002.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 128 months (mean 94 months).</p> <p><b>Follow-up schedule:</b> 6, 12, 18, and 24 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged <math>\leq 75</math> years; discharged from hospital (index event) after AMI, PCI, CABG; living in hospital catchment area; being healthy enough to be referred back to general practitioner within 1 year after admission; not having participated in similar programmes; Swedish speaking; willing to participate in study and accept random group allocation</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> AMI (51%), CABG (34%), PCI (15%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 362; intervention: 192; comparator: 170.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: 62.0 <math>\pm</math> 7.9 years; comparator: 61.0 <math>\pm</math> 8.3</p>

	<p>years</p> <p><b>Men:</b> total: 77%; intervention: 78%; comparator: 75%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> CBT programme delivered using a manual included 5 key components with specific goals: education, self-monitoring, skills training, cognitive restructuring, and spiritual development. Each session had a specific theme, working material, and homework assignment. Simple diaries were used for self-monitoring of behaviours and reactions. Behavioural exercises (“drills”) were introduced early and were monitored and discussed in every session. The session format was: brief relaxation, reflections on the previous session, follow-up of homework assignment, introduction of new themes, and preparation of homework. The communication style of the therapist was oriented towards motivational interviewing rather than educational</p> <p><b>Treatment targets:</b> stress management; coping with stress; and reducing experience of daily stress, time urgency, and hostility</p> <p><b>Components:</b> CBT, education, self-monitoring, skills training, cognitive restructuring, and spiritual development</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (5-9 participants), separate groups for men and women</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>• length of session: 2 hours;</li> <li>• frequency/number of sessions: 20 sessions during 1 year/20;</li> <li>• total duration: 40 contact hours, over 1 year.</li> </ul> <p><b>Delivered by:</b> clinical psychologists and nurses, experts in CHD and working with people with CHD</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> NR.</p> <p><b>COMPARATOR:</b> usual care, defined as traditional risk factor optimisation efforts during follow-up</p> <p><b>Cointerventions:</b> NR.</p>
Outcomes	<p>Total mortality.</p> <p>Time to first recurrent CVD event.</p> <p>Time to first recurrent AMI.</p>
Source of funding	Swedish Medical Research Council, the Var dal foundation, the Swedish Council for Working Life and Social Research, the Swedish National Board of Health and Welfare, the Swedish Heart and Lung Association, by the Uppsala Primary Health Care Administration, and by Uppsala University
Conflicts of interest	Authors declared no conflict of interests.
Notes	
<b>Risk of bias</b>	
<b>Bias</b>	<p><b>Authors’ judgement</b></p> <p><b>Support for judgement</b></p>

Random sequence generation (selection bias)	Low risk	"The group allocation was based on the SAS "ranuni" function, providing random numbers with equal probability."
Allocation concealment (selection bias)	Low risk	"The procedure resulted in pre-prepared sealed envelopes, kept in a safe, with a serial number on the outside and a sheet of paper inside with the group allocation on the front and a blinding print on the back to prevent reading the group allocation sheet from the outside. After inclusion of a participant, the study monitor, a secretary who managed data handling and follow-up appointments and who was the only person with access to the randomisation envelopes, opened the next envelope in turn and noted the group allocation in the computerized monitoring logbook."
Blinding of outcome assessment (detection bias)	Low risk	Not clearly described - although all outcome data obtained from registries
Incomplete outcome data (attrition bias) All outcomes	Low risk	"...all "hard" outcome data were obtained from official registries, and the follow-up was complete until death or end of follow-up, minimizing the bias risk."
Selective reporting (reporting bias)	Low risk	All outcomes described in methods were reported in results.
Groups balanced at baseline	Low risk	"There were no significant baseline differences between the intervention and reference groups in the characteristics shown in <a href="#">Table 1</a> and no significant differences in the medical history variables ( <a href="#">Table 2</a> )."
Intention-to-treat analysis	Low risk	"All analyses were based on the intention-to-treat approach. As shown in <a href="#">Figure 1</a> , most individuals participated in all follow-up examinations, with a small group coming and going. The largest number of permanent dropouts from the study were attributable to death. In case of missed appointments among survivors, data from the most recent previous appointment were used until new values were available."

Groups received same cointerventions	Low risk	“The intervention group and the reference group both received traditional care, defined as traditional risk factor optimization efforts during follow-up. In addition, the intervention group participants entered the CBT intervention programme as soon as they were included in the trial.”
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## Jones 1996

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> UK.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (6).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 6 and 12 months.</p>
Participants	<p><b>Inclusion criteria:</b> discharged home from hospital within 28 days of confirmed MI, irrespective of age, sex, or previous cardiac history</p> <p><b>Exclusion criteria:</b> prolonged hospital stay (&gt; 28 days) and discharge to long-term institutional care</p> <p><b>Indication (% participants):</b> AMI (100%).</p> <p><b>Psychopathology:</b> clinically significant anxiety (32%) and depression (19%).</p> <p><b>Number randomised:</b> total: 2328; intervention: 1168; comparator: 1160.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: NR; comparator: NR.</p> <p><b>Men:</b> total: NR; intervention: NR; comparator: NR.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> rehabilitation programmes comprising psychological therapy, counselling, relaxation training, and stress management training over 7 weekly group outpatient sessions for participants and spouses. Principal objectives were to: give information about the heart condition and treatment to allay fears and reduce anxiety; increase awareness of stress and stressful situations; teach relaxation skills; improve responses to stressful situations and develop coping skills; promote positive adjustment to illness; and rebuild confidence in participants and spouses. Sessions included teaching, practical exercises with participant participation, group discussion, and individual counselling. The importance of practice between sessions was emphasised and participants were asked to keep records of progress with diaries of activity, stress, and relaxation</p> <p><b>Treatment targets:</b> risk education, disease adjustment, stress, anxiety, depression</p> <p><b>Components:</b> risk information, self-awareness/monitoring, relaxation, client-led discussion</p> <p><b>Treatment setting (number of sites):</b> hospital outpatient clinic (6).</p> <p><b>Modality (group size):</b> individual and group sessions (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>• length of session: 2 hours;</li> <li>• frequency/number of sessions: weekly/7;</li> <li>• total duration: 14 contact hours, over 7 weeks.</li> </ul> <p><b>Delivered by:</b> clinical psychologists and health visitors.</p>



	<b>Follow-up further reinforcement:</b> NR. <b>Cointerventions:</b> education. <b>COMPARATOR:</b> usual medical care. <b>Cointerventions:</b> NR.	
Outcomes	Total mortality. Non-fatal MI. Revascularisation (CABG and PCI). Anxiety (STAI). Depression ( <a href="#">DSSI/sAD 1976</a> ).	
Source of funding	British Heart Foundation and Welsh Office.	
Conflicts of interest	Authors declared no conflict of interest.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Only stated that participants were randomised.
Allocation concealment (selection bias)	Low risk	Participants randomised by a study coordinating centre, with knowledge only of the date of admission and eligibility for discharge, and no prognostic factors
Blinding of outcome assessment (detection bias)	Low risk	Interviewers were blind to treatment status.
Incomplete outcome data (attrition bias) All outcomes	Low risk	See <a href="#">Figure 1</a> . Of 2328 participants randomised, 12-month clinical follow-up was available for 2042 (94%) of surviving participants (intervention: 1029/1168 vs comparator: 1013/1160)
Selective reporting (reporting bias)	Low risk	Results data for all outcomes described in results section.
Groups balanced at baseline	Low risk	“In this series there were no important differences by age, sex, hospital, or baseline anxiety or depression.”
Intention-to-treat analysis	Low risk	“The intention-to-treat analysis might also dilute any true therapeutic effect...”

Groups received same cointerventions	High risk	The intervention included an education component that was not available to control participants
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## Koertge 2008

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Sweden.</p> <p><b>Dates participants recruited:</b> August 1996 to January 2000.</p> <p><b>Participants recruited (number of sites):</b> hospital (2).</p> <p><b>Maximum follow-up:</b> 2 years.</p> <p><b>Follow-up schedule:</b> 10 weeks, 1 year, and 1-2 years.</p>
Participants	<p><b>Inclusion criteria:</b> women aged <math>\leq 75</math> years who had AMI, PCI, or CABG</p> <p><b>Exclusion criteria:</b> unable to communicate in Swedish, participating in other research studies, not living in the hospital catchment area or had serious comorbidity that would preclude taking part in the 1-year intervention programme (e.g. malignancy or psychiatric disease)</p> <p><b>Indication (% participants):</b> AMI (57%), PCI (31%), CABG (32%).</p> <p><b>Psychopathology:</b> vital exhaustion, Maastricht Questionnaire <math>\geq 14</math> (intervention: 78%; comparator: 69%) and depressive symptoms, BDI <math>\geq 10</math> (intervention: 55%; comparator: 52%)</p> <p><b>Number randomised:</b> total: 247; intervention: 119; comparator: 128.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: <math>62 \pm 8.9</math> years; intervention: <math>61.4 \pm 9.1</math> years; comparator: <math>62.7 \pm 8.7</math> years</p> <p><b>Men:</b> total: 0%; intervention: 0%; comparator: 0%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> the stress management programme was based on cognitive behavioural principles with various strategies to be practised between every session. All sessions had elements of both education and discussions. The initial sessions were focused on teaching links between CHD and lifestyle, and the physiological stress response. Subsequent sessions aimed at teaching how to identify the physical, cognitive, affective, and behavioural stress responses using cognitive behavioural strategies. Strategies include replacing negative and irrational thoughts with alternative ones, practising a relaxed behaviour style as opposed to Type A behaviour, practising progressive relaxation techniques, assertive communication, and strategic problem-solving skills</p> <p><b>Treatment targets:</b> stress; also some attention to risk education, disease adjustment, anxiety, Type A behaviour, exhaustion, depression</p> <p><b>Components:</b> risk information, self-awareness/monitoring, relaxation, cognitive challenge/restructuring, homework</p> <p><b>Treatment setting (number of sites):</b> hospital (2).</p> <p><b>Modality (group size):</b> group (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 2 hours;</li> <li>frequency/number of sessions: weekly/10, then monthly/10;</li> <li>total duration: 40 contact hours, over 1 year.</li> </ul> <p><b>Delivered by:</b> NR.</p>

	<i>Follow-up further reinforcement:</i> NR. <i>Cointerventions:</i> education and usual medical care. <b>COMPARATOR:</b> usual medical care, including referral to comprehensive cardiac rehabilitation <i>Cointerventions:</i> NR.	
Outcomes	Total mortality. Depression (BDI). Stress (Everyday Life Stress Scale). Vital exhaustion (Maastricht Questionnaire).	
Source of funding	Ansgarius Foundation, the Belven Foundation, King Gustaf V's and Queen Victoria's Foundation, Swedish Heart and Lung Foundation, the Public Health Committee and EXPO-95 of Stockholm County Council, the Swedish Medical Research Council (project 19X-11629), the Vardal Foundation, Stockholm, Sweden	
Conflicts of interest	The authors declared no conflict of interest.	
Notes	Stress data reported in <a href="#">Blom 2009</a> .	
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	A random number table was used to create group assignments.
Allocation concealment (selection bias)	Low risk	"A person not in contact with patients allocated them. The result of the procedure was kept in sealed envelopes and given to the patients by research nurses."
Blinding of outcome assessment (detection bias)	Low risk	The person entering participants' data (paper-based questionnaires) in the computer had no knowledge about the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	All missing data adequately accounted for, and similar numbers of participants were missing from control and treatment groups
Selective reporting (reporting bias)	Low risk	All outcomes mentioned in the methods fully reported.
Groups balanced at baseline	High risk	"The patients in the intervention group had higher levels of vital exhaustion (intervention group: mean = 22.7 ± 10.6, median = 23.0, range = 0-42, control group: mean = 19.4 ± 9.6, median = 19.0, range = 0-42 P = 0.036, see <a href="#">Table 1</a> ."

Koertge 2008 (Continued)

Intention-to-treat analysis	Low risk	“Analyses on the effects of the intervention were based on intention-to-treat approach.”
Groups received same cointerventions	High risk	Intervention included an education component and usual medical and pharmacological care

Lie 2007

Methods	<p><b>Design:</b> single-centre prospective RCT.</p> <p><b>Country:</b> Norway.</p> <p><b>Dates participants recruited:</b> August 2003 to 2004.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 6 months.</p> <p><b>Follow-up schedule:</b> 6 weeks and 6 months.</p>
Participants	<p><b>Inclusion criteria:</b> elective CABG participants, aged 18-80 years, admitted to Ullevål University Hospital (Oslo, Norway) between August 2003 and 2004, physically and mentally capable of completing the study, read and understand the Norwegian language, resided within 3 hours of driving distance of Oslo</p> <p><b>Exclusion criteria:</b> undergone combined coronary and valve replacement surgery, emergency surgery, or repeat surgery; experienced complications related to surgery; required prolonged stay in intensive care units</p> <p><b>Indication (% participants):</b> elective CABG (100%).</p> <p><b>Psychopathology:</b> recruitment not based on psychopathology. Anxiety, HADS-A (intervention: 29%; comparator: 35%) and Depression, HADS-D (intervention: 15%; comparator: 22%)</p> <p><b>Number randomised:</b> total: 203; intervention: 101; comparator: 102. (18 (9%) lost to follow-up at 6 months. All results based on: total: 185; intervention: 93; comparator: 92)</p> <p><b>Age (mean ± SD):</b> total: NR; intervention: 62 years (range 39-77); comparator: 62 years (range 42-78)</p> <p><b>Men:</b> total: NR; intervention: 90%; comparator: 89%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> home-based intervention programme involved 2 nurse visits who had individualised the programme. First visit included: angina symptoms, medications, sexuality; contact details for further information or in an emergency; setting personal goals; and identifying coping strategies. The nurse suggested additional coping strategies and provided emotional support for participants struggling with anxiety or depression (or both). Information on coping strategies was documented in an intervention manual for the participants to consult before the second home visit. Second visit included: evaluation of goal attainment and to reassess anxiety, depression, and coping</p> <p><b>Treatment targets:</b> anxiety, depression, coping.</p> <p><b>Components:</b> psychoeducation, goal setting, coping strategies.</p> <p><b>Treatment setting (number of sites):</b> home-based (NR).</p> <p><b>Modality (group size):</b> individual, although significant others could be present.</p>

	<b>Dose:</b> <ul style="list-style-type: none"><li>length of session: 1 hour;</li><li>frequency/number of sessions: home visits 2 and 4 weeks after surgery/2;</li><li>total duration: 2 contact hours, over 4 weeks.</li></ul> <b>Delivered by:</b> critical care nurse. <b>Follow-up further reinforcement:</b> NR. <b>Cointerventions:</b> NR. <b>COMPARATOR:</b> standard discharge care: a short talk with the nurse/doctor, participants received information, and asked questions <b>Cointerventions:</b> NR.	
Outcomes	Hospitalisations. Anxiety (HADS-A). Depression (HADS-D). HRQoL (Seattle Angina Questionnaire, SF-36 Physical and Mental component scores reported by Lie et al. 2009)	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	"A randomisation code was developed with a computer random number generator."
Allocation concealment (selection bias)	Low risk	"A randomization code was developed with a computer random number generator. Once the patient had completed the informed consent process, an opaque envelope with sequential numbering and instructions was opened." In an associated paper (Lie et al. 2009) the authors described the code being generated by a statistician independent from the recruitment team, with the allocated codes placed into envelopes by a secretary
Blinding of outcome assessment (detection bias)	Low risk	"The questionnaires were mailed to the participants in both groups and returned to the investigator in pre-stamped envelopes. Thereafter, all data entries and analyses were performed without knowledge of group assignment."

**Lie 2007** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	“Two hundred three patients were included in the study; after 18 patients were lost to follow-up, 93 patients in the intervention group and 92 patients in the control group completed the study.”
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	Low risk	“The characteristics of the patients included in the study did not differ significantly between the two groups (Table 1).”
Intention-to-treat analysis	Low risk	“ITT [intention-to-treat] analysis was also performed in the present study and demonstrated results similar to those of per-protocol analysis.”
Groups received same cointerventions	Low risk	No other cointerventions.

**Mayou 2002**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> UK.</p> <p><b>Dates participants recruited:</b> January 1997 to March 1998.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 1, 3, and 12 months.</p>
Participants	<p><b>Inclusion criteria:</b> living in the region, aged <math>\leq 70</math> years, with a first or secondary infarction (clinical diagnosis)</p> <p><b>Exclusion criteria:</b> people unable to participate in trial procedures.</p> <p><b>Indication (% participants):</b> AMI (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 114; intervention: 54; comparator: 56.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 58.2 (SD NR) years; intervention: <math>57.9 \pm 7.4</math> years; comparator: <math>58.3 \pm 8.4</math> years</p> <p><b>Men:</b> total: 78%; intervention: 80%; comparator: 76%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> nurses applied behavioural techniques supported by a handbook. Individualised recommendations for lifestyle and secondary prevention were given, with advice on how they might best be achieved using cognitive behavioural principles. Individualised plans supplemented the more general information sheets that were provided. Partners were encouraged to attend</p> <p><b>Treatment targets:</b> risk education, behaviour change, disease adjustment; attention paid to anxiety and depression</p> <p><b>Components:</b> risk education, guidance on behaviour change, relaxation; some client-led</p>

	discussion <b>Treatment setting (number of sites):</b> hospital (1). <b>Modality (group size):</b> individual. <b>Dose:</b> <ul style="list-style-type: none"><li>length of session: NR;</li><li>frequency/number of sessions: NR/2-4 times;</li><li>total duration: mean 2.43 contact hours, total duration NR.</li></ul> <b>Delivered by:</b> cardiac nurses. <b>Follow-up further reinforcement:</b> following discharge, participants were telephoned to review progress towards goals and to discuss any problems or questions. Readmitted participants were seen on their wards <b>Cointerventions:</b> tailored education and usual medical care. <b>COMPARATOR:</b> usual medical care (structured exercise not available) including advice from medical and nursing staff, access to standard booklets, and a medical outpatient clinic follow-up at 6 weeks. Structured exercise was not routinely offered <b>Cointerventions:</b> NR.	
Outcomes	Anxiety and Depression combined score (HADS - total score). HRQoL (Dartmouth COOP scales).	
Source of funding	British Heart Foundation.	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Random number tables.
Allocation concealment (selection bias)	Low risk	Following completion of the baseline assessment, participants were randomised by the research nurse using a system of opaque sealed envelopes prepared using random number tables
Blinding of outcome assessment (detection bias)	Unclear risk	Research nurses (distinct from treatment team) took baseline measures, but follow-up scores obtained via postal questionnaires, and unclear how these were handled
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Throughout, an intention-to-treat approach was adopted.” All dropouts reported. For dichotomous outcomes, a conservative analysis was conducted with missing data counted as poor outcomes

**Mayou 2002** (Continued)

Selective reporting (reporting bias)	Unclear risk	All outcomes fully reported. However, no numerical data provided for the combined Type A measure (only subscales, of which some were and some were not significantly different)
Groups balanced at baseline	Low risk	Table 1 showed that all baseline characteristics and prognostic factors were similar in both groups at baseline (although no P values were given)
Intention-to-treat analysis	Low risk	"Throughout, an intention-to-treat approach was adopted."
Groups received same cointerventions	Low risk	Risk education was provided to both groups.

**McLaughlin 2005**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> September 2001 to August 2003.</p> <p><b>Participants recruited (number of sites):</b> hospital (2).</p> <p><b>Maximum follow-up:</b> 6 months.</p> <p><b>Follow-up schedule:</b> 2, 3, and 6 months.</p>
Participants	<p><b>Inclusion criteria:</b> ACS, aged <math>\geq 35</math> years, able to speak English, had access to a touch-tone phone, and had symptoms of depressive illness or anxiety (<math>&gt; 7</math> HADS-A or <math>&gt; 7</math> HADS-D)</p> <p><b>Exclusion criteria:</b> mental health care in the previous 3 months, psychoactive drug use or diagnosed substance abuse during the past year, or severe depression (<math>&gt; 15</math> HADS-D)</p> <p><b>Indication (% participants):</b> ACS (100%) including angina (9%), MI (37%), ischaemic heart disease (54%)</p> <p><b>Psychopathology:</b> eligibility criteria anxiety and depression (47%), depression only (39%), anxiety only (14%)</p> <p><b>Number randomised:</b> total: 100; intervention: 53; comparator: 47.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 60.2 (SD NR) years; intervention: <math>59.9 \pm 10.2</math> years; comparator: <math>60.7 \pm 9.8</math> years</p> <p><b>Men:</b> total: NR; intervention: 69%; comparator: 65%.</p> <p><b>Ethnicity (% white):</b> total: NR; intervention: 89%; comparator: 88%.</p>
Interventions	<p><b>INTERVENTION:</b> first telephone contact reviewed 8 fears commonly experienced by people living with chronic medical conditions: loss of control, loss of self-image, dependency, stigma, abandonment, anger, isolation, and fear of death. With the counsellor, participants identified barriers to adjustment to medical illness and rank ordered these. In sessions 2-6, participants and counsellors identified strategies to address these barriers. The counsellor reviewed progress toward goals with reinforcement and encouragement. A session log tracked the issues reviewed in each session</p>



	<p><b>Treatment targets:</b> disease adjustment; also some attention to anxiety, depression</p> <p><b>Components:</b> guidance on behaviour change, self-awareness/monitoring; also some cognitive challenge/restructuring, client-led discussion, emotional support, and homework</p> <p><b>Treatment setting (number of sites):</b> telephone-based intervention (NR).</p> <p><b>Modality (group size):</b> individual via telephone.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>length of session: 30 minutes;</li><li>frequency/number of sessions: NR/3-6;</li><li>total duration: 3 contact hours, over an 8-week period.</li></ul> <p><b>Delivered by:</b> doctoral-level clinicians (psychiatrist, clinical psychologist, and internist)</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> usual medical care.</p> <p><b>COMPARATOR:</b> usual medical care.</p> <p><b>Cointerventions:</b> control participants received a booklet on coping with cardiac illness typical of those given at hospital discharge</p>	
Outcomes	Total mortality. Anxiety (HADS-A). Depression (HADS-D).	
Source of funding	National Institute of Mental Health (Mental Health Services Research Program in Managed Care) and Robert Wood Johnson Foundation: McLaughlin Thomas	
Conflicts of interest	Authors declared no conflicts of interest.	
Notes	There was a significant decrease in depression scores, but mean baseline scores in the intervention group were 2 points higher, indicating a potential selection bias. (Note from previous update.)	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Coin flip.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Low risk	Baseline and follow-up measures were obtained via an interactive telephone system
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	“Statistical analyses consisted of descriptive and intent to treat modelling procedures.”
Selective reporting (reporting bias)	High risk	Anger (State-Trait Anger Expression Inventory) mentioned in the methods, but outcome data NR

Groups balanced at baseline	Low risk	"Table 1 indicates that at randomisation groups were balanced."
Intention-to-treat analysis	Low risk	"Statistical analyses consisted of descriptive and intent-to-treat modelling procedures."
Groups received same cointerventions	Unclear risk	The control group received a booklet on coping strategies that was "typically provided upon hospital discharge." It did not state if this was also given to intervention group participants, although it is likely as they were not formally recruited until posthospital discharge

## Merswolken 2011

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Sweden.</p> <p><b>Dates participants recruited:</b> May 2008 to December 2008.</p> <p><b>Participants recruited (number of sites):</b> hospital (2).</p> <p><b>Maximum follow-up:</b> 6 months.</p> <p><b>Follow-up schedule:</b> 6 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged <math>\leq 75</math> years, had a CHD, as defined by a history of MI or angiographically documented CHD, but no MI or ACS or CABG in last 3 months. Score <math>\geq 8</math> HADS-A</p> <p><b>Exclusion criteria:</b> preplanned CABG in the 6 months after inclusion, manifest cardiac arrhythmias or pacemaker, implantable cardioverter defibrillator, severe heart failure (LVEF <math>&lt; 35\%</math>), type 1 diabetes, chronic infections, alcohol or drug abuse, or a severe medical or psychiatric condition</p> <p><b>Indication (% participants):</b> CHD (100%).</p> <p><b>Psychopathology:</b> elevated levels of anxiety, <math>\geq 8</math> HADS-A (100%).</p> <p><b>Number randomised:</b> total: 62; intervention: 30; comparator: 32. (10 participants lost to follow-up so presented results are for complete data sets: total: 52; intervention: 25; comparator: 27)</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: <math>62.5 \pm 8.3</math> years; comparator: <math>59.8 \pm 7.5</math> years</p> <p><b>Men:</b> total: NR; intervention: 76%; comparator: 70%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> included: information on CHD management; information on symptoms of anxiety, stress, and bodily effects; teaching participants to monitor stress signs and stress management techniques; teaching techniques of cognitive restructuring to change the participants' distorted beliefs and interpretations of threatening symptoms and life situations; reflecting disease-associated changes in social relationships; and practising social communication skills</p> <p><b>Treatment targets:</b> anxiety and stress.</p> <p><b>Components:</b> risk education, stress management, cognitive restructuring, disease adjust-</p>

	ment <b>Treatment setting (number of sites):</b> NR (NR). <b>Modality (group size):</b> group (6-8 participants). <b>Dose:</b> <ul style="list-style-type: none"><li>length of session: 2 hours;</li><li>frequency/number of sessions: weekly/12 and then monthly/3;</li><li>total duration: 30 contact hours, over 6 months.</li></ul> <b>Delivered by:</b> 2 clinical psychologists and cardiologist. <b>Follow-up further reinforcement:</b> none. <b>Cointerventions:</b> none. <b>COMPARATOR:</b> participants received no intervention. <b>Cointerventions:</b> none.	
Outcomes	Anxiety (HADS-A). Depression (HADS-D).	
Source of funding	NR.	
Conflicts of interest	Authors declared no conflict of interest.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomisation assignments were made using a simple randomisation strategy (random numbers table)
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	High risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up: intervention: 5/30 (17%); control: 5/32 (16%)
Selective reporting (reporting bias)	Low risk	All outcomes described in methods were reported in results.
Groups balanced at baseline	Low risk	“Intervention and control groups were comparable in most of the sociodemographic, disease-related and psychological variables (table 1) except for significant differences in systolic blood pressure and use of calcium channel blockers and nitrates.”

Intention-to-treat analysis	Low risk	Per-protocol analysis presented. Intention-to-treat analysis not conducted for reported results, but: “we repeated all analyses based on the intention-to-treat principle applying LOCF [last observation carried forward] to replace missing values and did not find any change of our results.”
Groups received same cointerventions	Unclear risk	Usual care not described so could not be sure what was a cointervention

## Michalsen 2005

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Germany.</p> <p><b>Dates participants recruited:</b> July 2001 to December 2001.</p> <p><b>Participants recruited (number of sites):</b> hospital (2).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 1 year.</p>
Participants	<p><b>Inclusion criteria:</b> documented CAD after coronary angiography PCI, or stationary treatment for CAD</p> <p><b>Exclusion criteria:</b> participants who had had ACS or CABG during the previous 3 months, type 1 diabetes, a body mass index &gt; 33 kg/m<sup>2</sup>, manifest cardiac arrhythmias, heart failure, or a life-threatening comorbid condition</p> <p><b>Indication (% participants):</b> CAD (100%) including ≥ 1 of MI (51%), coronary bypass (32%), PCI (55%), implanted stent (42%), and 3-vessel disease (41%)</p> <p><b>Psychopathology:</b> clinical diagnosis of depression (3.8%).</p> <p><b>Number randomised:</b> total: 105; intervention: 51; comparator: 54.</p> <p><b>Age (mean ± SD):</b> total: 59.4 ± 8.6 years; intervention: 59.0 ± 8.7 years; comparator: 59.8 ± 8.6 years</p> <p><b>Men:</b> total: 77%; intervention: 79%; comparator: 76%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> comprehensive lifestyle therapy/stress reduction group. Techniques taught included mindfulness meditation, guided imagery, yoga breathing techniques, and body scan. Further elements included CBT (cognitive restructuring) and psychoeducational approaches (coping skills training). CBT included monitoring irrational automatic thoughts and generating alternative interpretations of situations. Programme included practical exercises aimed at developing attitudes of non-judging, acceptance, and patience. Each session included educational lectures about stress reduction, stress management, and nutritional therapy, followed by training and practising yoga, mindfulness meditation, body scan, and visualisations</p> <p><b>Treatment targets:</b> stress; also some attention paid to behaviour change.</p> <p><b>Components:</b> risk information, guidance on behaviour change, self-awareness/monitoring, relaxation, cognitive challenge/restructuring</p> <p><b>Treatment setting (number of sites):</b> initial retreat, then weekly sessions at hospital (2).</p> <p><b>Modality (group size):</b> group (10-12 participants).</p>

	<p><b>Dose:</b> programme started with a 3-day retreat followed by weekly 3-hour sessions for 10 weeks and thereafter by twice weekly 2-hour meetings</p> <ul style="list-style-type: none"><li>length of session: 3 hours and then 2 hours;</li><li>frequency/number of sessions: weekly/10, then twice weekly/20;</li><li>total duration: 96 contact hours, over 1 year.</li></ul> <p><b>Delivered by:</b> personnel who had undergone training and who had experience teaching these programmes for at least 2 years</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> Mediterranean-type diet recommended. Physical activity and exercise encouraged, but not taught formally as part of intervention</p> <p><b>COMPARATOR:</b> written advice about stress management.</p> <p><b>Cointerventions:</b> NR.</p>	
Outcomes	Total mortality. Revascularisation. Anxiety (STAI). Depression (BDI). HRQoL (SF-36 Physical and Mental component scores). Anger (STAXI). Perceived stress (Cohen Perceived Stress scale).	
Source of funding	The Alfried Krupp Foundation, Essen.	
Conflicts of interest	Authors declared no conflicts of interest.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Central computer-generated random assignments.
Allocation concealment (selection bias)	Unclear risk	“Randomization assignments were made by a central computer” but no mention made of concealment of allocation from investigators, e.g. during enrolment
Blinding of outcome assessment (detection bias)	Unclear risk	No mention made of how self-reported outcome assessments were collected and coded for analysis
Incomplete outcome data (attrition bias) All outcomes	Low risk	“Analyses included all patients for whom data were available at follow-up (per protocol-analysis).” Missing participants and reasons noted per-group

Michalsen 2005 (Continued)

Selective reporting (reporting bias)	Low risk	Data presented for all measures mentioned in the methods section
Groups balanced at baseline	Low risk	“Baseline characteristics were well balanced between groups (all p values for group dependence 1 0.1, except a trend (p = 0.06) for patients in the AOG [written advice only group i.e. controls] to have a higher body mass index (table 1).”
Intention-to-treat analysis	High risk	“We did not perform 'intention-to-treat' analysis.”
Groups received same cointerventions	Low risk	Both groups received risk advice.

Neves 2009

Methods	<p><b>Design:</b> RCT.</p> <p><b>Country:</b> Portugal.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> NR.</p> <p><b>Maximum follow-up:</b> 2 years.</p> <p><b>Follow-up schedule:</b> 2 years.</p>
Participants	<p><b>Inclusion criteria:</b> aged 40-80 years, CAD (stable angina or AMI).</p> <p><b>Exclusion criteria:</b> presence of neurological diseases; currently taking any antidepressive, antiepileptic, or relaxation medication. Participants who had a recurrent coronary event or who did not complete the programme were considered dropouts</p> <p><b>Indication (% participants):</b> stable angina (16%), AMI (84%).</p> <p><b>Psychopathology:</b> NR, although people taking antidepressants were excluded.</p> <p><b>Number randomised:</b> total: 81; intervention: 40; comparator: 41.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: 59.5 <math>\pm</math> 10.8 years; comparator: 59.6 <math>\pm</math> 10.8 years</p> <p><b>Men:</b> total: 85%; intervention: 85%; comparator: 85%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> standard cardiac rehabilitation plus a hospital-based relaxation therapy including: relaxation and imagery techniques, supervised group sessions, but no instructions were given for additional practice at home</p> <p><b>Treatment targets:</b> relaxation.</p> <p><b>Components:</b> Mitchell's simple physiological relaxation and imagery techniques</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1 hour;</li> <li>frequency/number of sessions: 3 sessions per week/36;</li> <li>total duration: 36 hours, over 12 weeks.</li> </ul> <p><b>Delivered by:</b> trained instructor.</p>

	<b>Follow-up further reinforcement:</b> NR. <b>Cointerventions:</b> standard cardiac rehabilitation programme offered as usual care <b>COMPARATOR:</b> cardiac rehabilitation programme including 4 counselling sessions (1 stress management, 1 smoking cessation, and 2 nutrition), and 3 sessions per week of exercise training for 12 weeks <b>Cointerventions:</b> NR.	
Outcomes	Cardiovascular-related hospital admissions: <ul style="list-style-type: none"><li>• total number of cardiac-related admissions;</li><li>• proportion of participants requiring admission.</li></ul>	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	No information just "...patients were randomly assigned..."
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	"Patients who had a recurrent coronary event or who did not complete the programme were considered dropouts. One patient initially assigned to the CPA [cardiac rehabilitation programme alone] group underwent cardiac revascularization surgery and was excluded from data analysis because of inability to participate. Thus, only 80/81 patients were subsequently considered for analysis."
Selective reporting (reporting bias)	Low risk	All outcomes listed in methods reported in results.
Groups balanced at baseline	Low risk	"There were no differences between the groups in the demographics and all parameters assessed at baseline."
Intention-to-treat analysis	Unclear risk	Not described.

Groups received same cointerventions	Low risk	All participants received the cardiac rehabilitation programme
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## O'Neil 2015

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Australia.</p> <p><b>Dates participants recruited:</b> December 2009 to February 2011.</p> <p><b>Participants recruited (number of sites):</b> hospital (6).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 6 and 12 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged 21-85 years, a clinical diagnosis of ACS (MI - ST elevation MI (STEMI) or non-STEMI) or unstable angina with confirmed CAD on angiogram), available for the duration of the study via the telephone, fluent in English, and scored 5-19 on PHQ-9</p> <p><b>Exclusion criteria:</b> cognitive impairment or a diagnosis of a psychiatric condition interfering with study involvement (e.g. bipolar illness, psychotic illness of any type, dementia, acute suicidality, severe personality disorder), participation in regular psychotherapy with a mental health professional at the time of hospital admission, terminal illness, or any inability to participate in an unsupervised tele-based mood and lifestyle intervention as confirmed by a treating clinician</p> <p><b>Indication (% participants):</b> 100% ACS.</p> <p><b>Psychopathology:</b> 100% depression (PHQ-9 score 5-19).</p> <p><b>Number randomised:</b> total: 121; intervention: 61; comparator: 60.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 60 (SD NR) years; intervention: 61.0 <math>\pm</math> 10.2 years; comparator: 58.9 <math>\pm</math> 10.7 years</p> <p><b>Men:</b> total: NR; intervention: 74%; comparator: 77%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> within 2 weeks of screening, participants received information via telephone-based structured intervention sessions including: short- and long-term goal setting to improve mental health and CVD risk factor profiles using motivational interviewing, goal setting, behavioural activation, and cognitive restructuring. Participants received a handbook containing project-specific and general health resources, session activities, CVD risk factor goals, and monitoring forms and recording sheets used for tracking mood and thoughts</p> <p><b>Treatment targets:</b> mental health, depression, and CVD risk profiles.</p> <p><b>Components:</b> CBT, motivational interviewing, goal setting, behavioural activation, and cognitive restructuring</p> <p><b>Treatment setting (number of sites):</b> hospital (6).</p> <p><b>Modality (group size):</b> individual, by telephone.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 30-40 minutes (mean: 48.4 minutes);</li> <li>frequency/number of sessions: varied (more in first 3 months) over 6 months/10 (median: 8);</li> <li>total duration: mean total length of exposure over 6 months: 384 minutes.</li> </ul> <p><b>Delivered by:</b> psychologists with a minimum of 2 years clinical CBT experience</p>



	<i>Follow-up further reinforcement:</i> NR. <i>Cointerventions:</i> usual medical care. <b>COMPARATOR:</b> usual medical care via their healthcare providers. <i>Cointerventions:</i> NR.	
Outcomes	Depression (Cardiac Depression Scale, PHQ-9). HRQoL (SF-12 Physical and Mental component scores).	
Source of funding	Australian Government Department of Health and Ageing Grant under the Sharing Health Care Initiative and a grant from beyondblue: the national depression and anxiety initiative Neither funding body had input into the conduct of the study. AO was supported by a Post Graduate Award from the Heart Foundation (PP 08M4079) while undertaking this work and was supported by a Fellowship from the National Health and Medical Research Council (#1052865). KS was supported by an Australian Research Council (ARC) Future Fellowship (FT991524). Trial Registration Number: ACTRN12609000386235	
Conflicts of interest	David Hare developed the Cardiac Depression Scale, and received research, fellowship, and consultancy funds from the National Health and Medical Research Council, the National Heart Foundation of Australia, the Austin Medical Research Foundation, beyondblue, and Diabetes Australia. He has received payment for research projects, consultancies, travel, advisory board memberships and lectures from industry including Abbott, Amgen, AstraZeneca, Biotronic, BMS, Boehringer Ingelheim, CSL-Biotherapies, Hoffmann-LaRoche, Hospira, Lundbeck (Denmark), Medtronic, Menarini, Merck KA (Germany), Merck (US), MSD, Pfizer, Roche, Sanofi- Aventis, Servier and Wyeth	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	“Stratified randomization was performed using a separate block randomization list that was generated for each stratum or study group. Following the completion of Time 1 data collection, randomization occurred, which was integrated into the web-based database.”
Allocation concealment (selection bias)	Low risk	“The randomization schedule was concealed from investigators and was stratified by Composite International Diagnostic Interview (CIDI) assessment (current MDD [major depressive disorder] vs not MDD) to ensure that the distribution of MDD cases between groups was even.”

Blinding of outcome assessment (detection bias)	Low risk	"The research assistants who administered telephone questionnaires were blinded to participants' study group and participants in turn were asked not to reveal the group to which they were randomized."
Incomplete outcome data (attrition bias) All outcomes	High risk	30/121 (25%) lost to follow-up/withdrew by 12 months.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	Low risk	"At baseline, no statistically significant group imbalances were observed with two exceptions: a significantly higher proportion of intervention participants had visited a general practitioner (GP) in the past 6 months and they were born in Australia (Tables 1 and 2)."
Intention-to-treat analysis	Low risk	"Analyses were based on intention to treat."
Groups received same cointerventions	Low risk	As described in the study conditions.

## Oldenburg 1985

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Australia.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 3-6 and 12 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged &lt; 70 years admitted to hospital following first AMI over a 12-month period. No identified levels of psychopathology prior to intervention</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> MI (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p>Participants randomised to 3 groups: intervention 1: counselling, education, and relaxation; intervention 2: Education; and comparator: relaxation group</p> <p><b>Number randomised:</b> total: 46; intervention 1: 16; intervention 2: 16; comparator: 14</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 56 (SD NR) years; intervention 1: 55.4 <math>\pm</math> 8.4 years; intervention 2: 56.7 <math>\pm</math> 7.2 years; comparator: 53.9 <math>\pm</math> 12.6 years</p> <p><b>Men:</b> total: 89%; intervention 1: NR; intervention 2: NR; comparator: NR</p> <p><b>Ethnicity (% white):</b> NR.</p>

Interventions	<p><b>INTERVENTION 1 'counselling group':</b> received individual counselling, relaxation training, and education (see 'education group' below). The first session took place within 48 hours of admission when the relaxation audiotape was also provided. The 3 education tapes were given to participants on subsequent days. Each counselling session focused on the participant's fears and anxieties, and discussed progress made with the relaxation and education tapes as well as behavioural strategies that could be employed in changing coronary risk factors on discharge from the hospital</p> <p><b>INTERVENTION 2 'education group':</b> received standardised educational materials, delivered via audiotape, describing primary and secondary prevention coronary risk factors and strategies for modifying behaviours. Progress muscular relaxation tapes were also provided</p> <p><b>Treatment targets:</b> impact of MI on functioning and psychological wellbeing; risk factor modification (in particular, Type A behaviour), relaxation</p> <p><b>Components:</b> counselling, relaxation, and risk factor education.</p> <p><b>Treatment setting (number of sites):</b> hospital inpatient (1).</p> <p><b>Modality (group size):</b> individual.</p> <p><b>Dose: intervention 1 'counselling group':</b></p> <ul style="list-style-type: none"><li>length of session: 45 minutes;</li><li>frequency/number of sessions: NR/6-10;</li><li>total duration: at least 6 months.</li></ul> <p><b>Delivered by:</b> therapist and audiotapes</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> education.</p> <p><b>Dose: intervention 2 'education group':</b></p> <ul style="list-style-type: none"><li>length of session: NR;</li><li>frequency/number of sessions: 3 audiotapes, 1 progressive relaxation tape;</li><li>total duration: NR.</li></ul> <p><b>Delivered by:</b> audiotapes.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> NR.</p> <p><b>COMPARATOR:</b> usual medical care.</p> <p><b>Cointerventions:</b> NR.</p>	
Outcomes	<p>Total mortality.</p> <p>Revascularisation (cardiac surgery).</p> <p>Hospital admission (MI related, and unrelated acute admissions)</p> <p>Heart attack Inventory (including STAI), although no data reported at level of individual measures</p> <p>Return to work.</p>	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Random sequence generation (selection bias)	High risk	Quasi-randomisation. Alternative allocation of all participants in each month of the study
Allocation concealment (selection bias)	High risk	Quasi-randomisation. Alternative allocation of all participants in each month of the study
Blinding of outcome assessment (detection bias)	Unclear risk	States therapists were not involved in any of the data collection, but no further details provided
Incomplete outcome data (attrition bias) All outcomes	Low risk	Of 46 participants randomised (intervention 1: 16; intervention 2: 16; comparator: 14), 5 died during the study and all but 1 of the survivors were interviewed at the final 12-month follow-up
Selective reporting (reporting bias)	Low risk	Results for all outcomes collected were reported.
Groups balanced at baseline	Low risk	“Group means for measures of morbidity at admission are shown in <a href="#">Table 1</a> . One-way analysis of variance (ANOVAs) yielded no significant differences between means on any of these measures, although there were a number of trends to suggest that the counselling group and to a lesser extent the education group might have a worse prognosis than the control group.”
Intention-to-treat analysis	Unclear risk	Analysis plan did not state how data would be analysed, and results did not indicate if participants were able to cross over between groups
Groups received same cointerventions	Low risk	“Over the duration of this study, there was no other systematic, or routine, psychological or educational intervention provided to MI patients either in the hospital or after discharge.”

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Finland.</p> <p><b>Dates participants recruited:</b> September 2004 to January 2007.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 18 months.</p> <p><b>Follow-up schedule:</b> 6 and 18 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged &lt; 75 years, AMI, knowledge of Finnish to complete the questionnaires, troponin T level &gt; 0.03 µg/L, and at least 1 of 3 criteria for an AMI: typical clinical presentation, presence of new ischaemic ECG changes, or new diagnostic findings in imaging, e.g. echocardiogram</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> MI (100%).</p> <p><b>Psychopathology:</b> depressive symptoms, BDI ≥ 10 (36%).</p> <p><b>Number randomised:</b> total: 103; intervention: 51; comparator: 52.</p> <p><b>Age (mean ± SD):</b> total: 59.6 (SD NR) years; intervention: 58.1 ± 10.4 years; comparator: 61.2 ± 9.7 years</p> <p><b>Men:</b> total: 71%; intervention: 75%; comparator: 67%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> interpersonal counselling included: a starting, encouragement, and ending phase focusing on the participant's current psychosocial functioning. The intervention form included structured details of interpersonal counselling for follow-up as well as notes on other considerations besides interpersonal counselling. In 90% of the cases, the focus was on role transition, including changes in life status</p> <p><b>Treatment targets:</b> depressive symptoms and distress.</p> <p><b>Components:</b> interpersonal counselling, psychosocial functioning, role transition, and changes in life status</p> <p><b>Treatment setting (number of sites):</b> hospital, telephone (1).</p> <p><b>Modality (group size):</b> individual.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1st session: 30 minutes (face-to-face); others: 20 minutes (telephone);</li> <li>frequency/number of sessions: NR/1-6 sessions (mean 4.6 ± 1.5);</li> <li>total duration: NR.</li> </ul> <p><b>Delivered by:</b> psychiatric nurse.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> standard care.</p> <p><b>COMPARATOR:</b> standard care after MI included: spoken and written instructions for control visits and prescriptions after MI, and guidance on how to find non-psychiatric and psychiatric healthcare services when needed</p> <p><b>Cointerventions:</b> NR.</p>
Outcomes	<p>Depression (BDI).</p> <p>HRQoL (EQ-5D).</p> <p>Distress (Symptoms Checklist-25).</p>
Source of funding	NR.
Conflicts of interest	Authors declared no conflict of interest.

**Oranta 2010** (Continued)

Notes	EQ-5D results reported in Oranta 2013.	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random sequence generation not described.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up: intervention: 3/51 (6%) ; control: 9/52 (17%)
Selective reporting (reporting bias)	Low risk	Results for all outcomes collected were reported.
Groups balanced at baseline	Low risk	“There was no significant difference between the intervention and control groups at baseline in marital status, living alone or with someone, depressive symptoms or number of depressive patients, distress or number of patients with distress, retirement, previous MI, profession, other long-term diseases or smoking status.”
Intention-to-treat analysis	Low risk	“The data from this study were analysed within an intent-to-treat framework.”
Groups received same cointerventions	Low risk	Both groups received standard care; no cointerventions described

**Peng 2005**

Methods	<p><b>Design:</b> RCT.</p> <p><b>Country:</b> China.</p> <p><b>Dates participants recruited:</b> January 1999 to December 2001.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up :</b> 1 year.</p> <p><b>Follow-up schedule:</b> 4 weeks (self-reported measures), 1 year (unstable angina, MI, 'sudden' death)</p>
Participants	<p><b>Inclusion criteria:</b> inpatients with clinically established CHD.</p> <p><b>Exclusion criteria:</b> people with a history of mental illness, a serious cognitive disorder, who have a serious condition, but uncooperative with physical examination, or too</p>

	<p>unwell to sign informed consent forms</p> <p><b>Indication (% participants):</b> MI (19%; 26/136), angina (45%; 61/136), arrhythmia (26%; 35/136), and heart failure (10%; 14/136)</p> <p><b>Psychopathology:</b> none.</p> <p><b>Number randomised:</b> total: 139; intervention: 72; comparator: 67.</p> <p><b>Age (mean ± SD):</b> total: 67.0 ± 13.0 years; intervention: 66.0 ± 10.0 years; comparator: 64.0 ± 10.0 years</p> <p><b>Men:</b> total: 63%; intervention: 68%; comparator: 75%.</p> <p><b>Ethnicity (% white):</b> NR.</p>	
Interventions	<p><b>INTERVENTION:</b> psychotherapy included: psychological support and explanation; relaxation measures to ease the negative emotions; instructions and corrections of wrong perception, bad behaviour mode, and coping method; and antianxiety medicine for participants with moderate and severe anxiety</p> <p><b>Treatment targets:</b> negative emotions associated with CHD, relaxation.</p> <p><b>Components:</b> psychotherapeutic approach included relaxation, emotional support, and cognitive-behavioural exercises in recognising unhealthy thought patterns and behaviours</p> <p><b>Treatment setting (number of sites):</b> NR.</p> <p><b>Modality (group size):</b> NR.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>length of session: 30 minutes;</li><li>frequency/number of sessions: 3 per week/2-4 weeks;</li><li>total duration: 3-6 contact hours, over 4 weeks.</li></ul> <p><b>Delivered by:</b> physicians and nurses.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> antianxiety medication (participants with moderate or severe anxiety, as required) and usual medical care</p> <p><b>COMPARATOR:</b> usual care.</p> <p><b>Cointerventions:</b> NR.</p>	
Outcomes	Coronary ischaemic-related events as a composite of unstable angina, AMI, and sudden death (individual event rates NR)	
Source of funding	Not translated.	
Conflicts of interest	Not translated.	
Notes	The baseline characteristics were reported for 136/139 of the participant sample	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Unclear risk	Not described.

**Peng 2005** (Continued)

Blinding of outcome assessment (detection bias)	Unclear risk	Not described.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 3 participants lost to follow-up across 1 year.
Selective reporting (reporting bias)	Low risk	Results for all outcomes collected were reported.
Groups balanced at baseline	Low risk	“Comparison of baseline data: There is no significant difference in the age, gender, course of disease, degree of education and profession ( $P>0.05$ ).”
Intention-to-treat analysis	Low risk	Not stated explicitly, although 71 in psychotherapy and 65 in non-psychotherapy were analysed (i.e. 3 participants lost to follow-up) in the groups that they were assigned
Groups received same cointerventions	Unclear risk	Unclear. Intervention group received anti-anxiety medication where indicated, but it was unclear whether this was part of usual medical care available to both intervention and comparator groups

**Rahe 1979**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> October 1971 to June 1972.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 7 years.</p> <p><b>Follow-up schedule:</b> 6, 18, 36, and 48 months.</p>
Participants	<p><b>Inclusion criteria:</b> surviving first MI, aged &lt; 60 years, able to return to work, who resided in the San Diego area, and planned to remain there for <math>\geq 3</math> years</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> first MI (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 44; intervention: 22; comparator: 22.</p> <p><b>Age (mean):</b> total: NR; intervention 50.9 (SD NR) years; comparator: 55.2 (SD NR) years</p> <p><b>Men:</b> total: 75%; intervention: 85%; comparator: 94%.</p> <p><b>Ethnicity (% white):</b> total: 100%.</p>



Interventions	<p><b>INTERVENTION:</b> material covered in the 6 sessions included: life stress and the onset of MI; the contribution of physical and psychological risk factors to CHD; coronary-prone behaviour; home problems; and return to work. Group sessions were educational with active discussion centred upon the problems inherent in optimal rehabilitation. The sessions were supportive rather than critical of long-standing lifestyles. Occasionally, “behavioural prescriptions” were given to encourage participants to develop new approaches to current life problems</p> <p><i>Treatment targets:</i> risk education; attention to behaviour change.</p> <p><i>Components:</i> risk information, client-led discussion; some guidance on behaviour change</p> <p><i>Treatment setting (number of sites):</i> hospital outpatient (1).</p> <p><i>Modality (group size):</i> group (2-8 participants).</p> <p><i>Dose:</i></p> <ul style="list-style-type: none"><li>• length of session: 90 minutes;</li><li>• frequency/number of sessions: once every 2 weeks/4-6;</li><li>• total duration: 9 contact hours, over 12 weeks.</li></ul> <p><i>Delivered by:</i> therapists (including first-year residents in internal medicine, hospital corpsmen, a medical student, and a chief cardiologist)</p> <p><i>Follow-up further reinforcement:</i> NR.</p> <p><i>Cointerventions:</i> risk factor education and dietetic advice.</p> <p><b>COMPARATOR:</b> usual medical care.</p> <p><i>Cointerventions:</i> risk factor education and dietetic advice.</p>	
Outcomes	Total mortality. Non-fatal MI. Revascularisation (CABG). Depression (clinical judgement by a psychiatrist interviewer) Return to work.	
Source of funding	Naval Medical Research and Development Command, Department of the Navy, under Research Work Unit	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Stated that the participants were randomly allocated; no further details
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Not described.

Incomplete outcome data (attrition bias) All outcomes	Low risk	Of the original 61 participants, 3- to 4-year morbidity data were available for 52/54 (95%) of those who had not died
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	Low risk	"Analysis of age, cigarette smoking, height, weight, Norris Prognostic Index* (all by one-way analysis of variance), location of infarct and other demographic dimensions (all by chi-square) indicated no significant differences between the 3 groups."
Intention-to-treat analysis	High risk	Data from dropouts were not included in the analyses.
Groups received same cointerventions	Low risk	Both groups received risk factor education and dietetic advice

## Rakowska 2015

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Poland.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 2.5 years.</p> <p><b>Follow-up schedule:</b> 10 weeks, 1 year, and 2.5 years.</p>
Participants	<p><b>Inclusion criteria:</b> diagnosis of first non-fatal MI; having increased levels of perceived stress in connection with psychosocial stress-related problems; and willingness to receive psychological help to control psychosocial stress-related problems</p> <p><b>Exclusion criteria:</b> severe mental problems (e.g. alcohol dependence or a psychosis)</p> <p><b>Indication (% participants):</b> 100% MI.</p> <p><b>Psychopathology:</b> 100% high or moderate levels of stress.</p> <p><b>Number randomised:</b> total: 81; intervention: 41; comparator: 40.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: 53.6 <math>\pm</math> 4.9 years; comparator: 53.4 <math>\pm</math> 4.3 years</p> <p><b>Men:</b> total: NR; intervention: 58%; comparator: 62%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> brief strategic therapy based on cybernetics: general strategy of solving psychosocial problems is to prevent people from using their problem-maintaining ineffective solutions by getting them to behave in a way opposite to the ineffective one. First, the most disruptive, stress-producing problem and the problem-maintaining behaviours were identified by the participant. Then the behaviour that is opposite to the participant's problem-maintaining behaviour was identified by the therapist. Participants had homework assignments. When a problem was solved, the therapists used relapse</p>

	<p>techniques to prevent reoccurrence of the problem</p> <p><b>Treatment targets:</b> chronic stress levels and ineffective coping skills.</p> <p><b>Components:</b> cybernetics, problem solving using counterintuitive methods. Retraining participant's natural 'ineffective' responses to psychosocial problems</p> <p><b>Treatment setting (number of sites):</b> hospital (1).</p> <p><b>Modality (group size):</b> individual.</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>length of session: 1 hour;</li><li>frequency/number of sessions: weekly/10;</li><li>total duration: 10 hours.</li></ul> <p><b>Delivered by:</b> 4 clinical psychologists, supervised by a senior brief strategic therapist</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> usual care including medication therapy, educational materials, and offered participation in structured exercise (see below)</p> <p><b>COMPARATOR:</b> usual care including postdischarge medication therapy according to their participant-focused care plan, written information about cardiac risk factors, and guidance on unhealthy behaviour change. All participants also offered 12-week exercise training that included 1 weekly supervised session</p> <p><b>Cointerventions:</b> none.</p>	
Outcomes	<p>Total cardiovascular events.</p> <p>Fatal or non-fatal (or both) MI.</p> <p>HRQoL (SF-36 Physical and Mental components scores).</p> <p>Perceived stress (Cohen Perceived Stress Scale, PSS-10).</p>	
Source of funding	Faculty of Psychology, University of Warsaw, Poland, for statutory research (grant number 144525/2009)	
Conflicts of interest	Authors declared no conflict of interest.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	"A random number table was used to create group assignments."
Allocation concealment (selection bias)	Low risk	"The outcome of the randomization was put in a sealed envelope, and patients who were admitted to the current study received these envelopes after the baseline interview."
Blinding of outcome assessment (detection bias)	Low risk	"A pair of investigators, blind to condition, conducted outcome assessments."

**Rakowska 2015** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Low risk	6/81 participants withdrew from the study.
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	Low risk	Table 1 data.
Intention-to-treat analysis	Low risk	“All analyses were based on intention-to-treat approach principles. Scores of all patients were included in the analyses. Missing scores were replaced by the last observed score.”
Groups received same cointerventions	Low risk	“Most of them were offered attendance at a 12-week exercise training that included one weekly supervised session; 48.78% of patients in the BST [brief strategic therapy] condition and 40.00% patients in the UC [usual care] condition underwent the training.”

**Roncella 2013**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Italy.</p> <p><b>Dates participants recruited:</b> June 2005 to January 2011.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 6 months and 1 year (although only 1-year data reported).</p>
Participants	<p><b>Inclusion criteria:</b> aged <math>\leq 70</math> years, admitted with an AMI receiving treatment with primary or urgent PCI of the culprit lesion, within 12 hours of the onset of a STEMI (primary PTCA), or within 48 hours in people with a non-STEMI (urgent PTCA). In cases of multivessel disease, complete revascularisation had to be achieved before discharge from hospital</p> <p><b>Exclusion criteria:</b> NR.</p> <p><b>Indication (% participants):</b> STEMI: 77.7%; non-STEMI: 22.3%. (note only STEMI reported - the figures for non-STEMI extrapolated)</p> <p><b>Psychopathology:</b> 40% had <math>\geq 10</math> on BDI at baseline.</p> <p><b>Number randomised:</b> total: 94; intervention: 49; comparator: 45.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: <math>55.0 \pm 9.0</math> years; comparator: <math>55.0 \pm 8.0</math> years</p> <p><b>Men:</b> total: 89%; intervention: 91%; comparator: 87%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> short-term psychotherapy based on the ontopsycho logical method included individual and group sessions. Individual meetings included: personal history, as emotionally lived by the participant, and on understanding basic expression of the uncon-</p>

	<p>scious dimension, through the interpretation of body and oneiric language. Group sessions to which partners were invited included: educational cardiological therapy (which included a broader explanation of MI and atherosclerotic processes, while accentuating the importance of cardiac risk factor prevention/reduction and lifestyle changes); music-guided breathing and muscular relaxation; comprehension of body signals; elements of oneiric language; and attention to specific partner/relationship issues</p> <p><b>Treatment targets:</b> “a psychotherapeutic intervention must improve global health to be considered effective.”</p> <p><b>Components:</b> short-term psychotherapy based on the ontopsychoanalytic method, education, relaxation</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> individual for months 1-3; group for months 4-6 (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>length of session: individual: 1 hour; group: 2 hours;</li><li>frequency/number of sessions: individual: 3 months/3-10 (as needed); group: monthly/3;</li><li>total duration: incomplete information to calculate contact hours, over 6 months.</li></ul> <p><b>Delivered by:</b> psychotherapist.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> usual cardiac rehabilitation care.</p> <p><b>COMPARATOR:</b> usual care included: being offered cardiac rehabilitation involving educational training and lifestyle change recommendations</p> <p><b>Cointerventions:</b> none.</p>	
Outcomes	Total mortality. Cardiac mortality. Non-fatal MI. Depression (BDI). HRQoL (MacNew Questionnaire). Measures of stress (self-evaluation test, assessing global psychological distress) Vital exhaustion (Modified Maastricht Questionnaire).	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes	Study primary outcome was the net cumulative incidence of new cardiological events (MI death, stroke, any revascularisation procedure, life-threatening ventricular arrhythmias, and recurrence of typical angina pectoris) and occurrence of any clinically significant new comorbidity	
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	“To minimize potential imbalance between the two groups and resultant confounding that might affect outcomes, randomization was performed in blocks (according to pa-

		tient age, and the type and location of the infarction) within one week after discharge from the intensive care unit."
Allocation concealment (selection bias)	Low risk	"To conceal the sequence of allocation, individual allocation to treatment was reported in case-report forms, which were sealed in envelopes and subdivided into different boxes according to randomization blocks. At the time of randomization, the relevant envelope was then given to the attending physician and the case-report form could then be unsealed revealing treatment allocation."
Blinding of outcome assessment (detection bias)	Low risk	"All data were collected using specific case-report forms and peer reviewed at one-year follow-up, with clinical adverse events adjudicated by a committee composed of three cardiologists (CP, VP, and FP) blinded to study arm allocation."
Incomplete outcome data (attrition bias) All outcomes	Low risk	49/54 intervention and 45/47 comparator provided data at 1 year follow-up
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	Low risk	"The two groups were balanced in terms of demographics, as well as in clinical, angiographic and psychometric characteristics."
Intention-to-treat analysis	Low risk	"Unless otherwise specified, all study data were analyzed on an intention-to treat basis."
Groups received same cointerventions	Low risk	"The choice of drug therapy in the acute and chronic phases was left to the treating physician's discretion. Administration of psycho-active drugs was not part of the protocol; but, in patients already being treated, psychiatric drugs were not discontinued after enrolment."

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> March 1998 to April 2003.</p> <p><b>Participants recruited (number of sites):</b> hospitals, disease registers (NR).</p> <p><b>Maximum follow-up:</b> 9.3 years.</p> <p><b>Follow-up (mean <math>\pm</math> SD):</b> total: <math>5.4 \pm 2.4</math> years; intervention: <math>5.3 \pm 2.3</math> years; comparator: <math>5.4 \pm 2.5</math> years</p> <p><b>Follow-up schedule:</b> 3 and every 6 months for clinical events and annually for psychosocial distress</p>
Participants	<p><b>Inclusion criteria:</b> black men and women with angiographic evidence of at least 1 coronary artery with <math>&gt; 50\%</math> stenosis</p> <p><b>Exclusion criteria:</b> AMI, stroke, or coronary revascularisation within the previous 3 months; chronic heart failure with ejection fraction <math>&lt; 20\%</math>; cognitive impairment; and non-cardiac life-threatening illness</p> <p><b>Indication (% participants):</b> CAD (100%).</p> <p><b>Psychopathology:</b> NR.</p> <p><b>Number randomised:</b> total: 201; intervention: 99; comparator: 102.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: NR; intervention: <math>59.9 \pm 10.7</math> years; comparator: <math>58.4 \pm 10.5</math> years</p> <p><b>Men:</b> total: NR; intervention: 59%; comparator: 56%.</p> <p><b>Ethnicity (% white):</b> total: 0%; intervention: 0%; comparator: 0%.</p>
Interventions	<p><b>INTERVENTION:</b> the transcendental meditation technique was described as a simple, natural, effortless procedure that was practised 20 minutes twice a day while sitting comfortably with eyes closed. During the practice, it was reported that ordinary thinking processes settle down, and a distinctive wakeful hypometabolic state characterised by neural coherence and physiological rest was gained. Standard teaching materials and format were used. The transcendental meditation technique was taught in a 7-step course of instruction comprising <math>6 \times 1.5</math>- to 2-hour individual and group meetings</p> <p><b>Treatment targets:</b> stress reduction.</p> <p><b>Components:</b> transcendental meditation.</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> individual and group (NR).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: supervised sessions 1.5-2 hours, self-directed 20 minutes;</li> <li>frequency/number of sessions: supervised NR/6, self-directed twice a day/NR;</li> <li>total duration: insufficient information to calculate contact hours, duration up to 9.3 years (total mean: <math>5.4 \pm 2.4</math>; intervention: <math>5.3 \pm 2.3</math> comparator: <math>5.4 \pm 2.5</math>).</li> </ul> <p><b>Delivered by:</b> instructor certified by Maharishi Foundation USA.</p> <p><b>Follow-up further reinforcement:</b> follow-up and maintenance meetings were held weekly for the first month, twice weekly for the 2 months, and monthly thereafter for the remainder of phases 1 and 2</p> <p><b>Cointerventions:</b> access to usual medical care.</p> <p><b>COMPARATOR:</b> the control intervention was a cardiovascular health education programme designed to match the format of the experimental intervention for instructional time, instructor attention, participant expectancy, social support, and other non-specific factors. The content was based on standard, published materials. The instructors were professional health educators. The health education participants were advised to spend</p>

	at least 20 minutes a day at home practising heart-healthy behaviours (exercise, healthy meal preparation, and non-specific relaxation) <b>Cointerventions:</b> NR. Participants continued usual medical care.	
Outcomes	Total mortality. Cardiac mortality. Revascularisation (CABG and PTCA, with or without stenting). Fatal and non-fatal MI. Other fatal or non-fatal (or both) cardiovascular events. Depression (Center for Epidemiological Studies Depression Scale)	
Source of funding	National Institutes of Health-National Heart, Lung and Blood Institute	
Conflicts of interest	Dr Schneider served as an investigator on research grants from the National Institutes of Health and US Department of Defense and is a consultant to Maharishi Foundation USA, a non-profit educational organisation. Dr Grim’s spouse was president and sole owner of Shared Care Research and Education Consulting. Dr Rainforth served as an investigator on research grants from the National Institutes of Health and US Department of Defense and his spouse was an independent contractor to Maharishi Foundation, USA. Dr Nidich served as an investigator on research grants from the National Institutes of Health, US Department of Defense and David Lynch Foundation and his spouse was an independent contractor to Maharishi Foundation, USA. Dr Gaylord-King served as an investigator on research grants from the National Institutes of Health, US Department of Defense and GMDO, a non-profit organisation. Dr Salerno served as an investigator on research grants from the National Institutes of Health and US Department of Defense. The other authors reported no conflicts	
Notes		
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	“Subjects were randomly assigned to either the TM [transcendental meditation] or health education (HE) arms using a stratified block design.”
Allocation concealment (selection bias)	Low risk	“Random allocation was performed by the study biostatistician who concealed the allocation schedule and conveyed the assignments to the study coordinator.”
Blinding of outcome assessment (detection bias)	Low risk	“Investigators, data collectors, and data management staff were blinded to group assignment.”



Incomplete outcome data (attrition bias) All outcomes	High risk	Lost to follow-up: intervention: 25/99 (25%); comparator: 23/102 (23%) The number and reasons for dropouts and withdrawals were properly described, but were relatively high in number
Selective reporting (reporting bias)	Low risk	All outcomes described in methods were reported in the results section
Groups balanced at baseline	Low risk	"The groups were generally similar at baseline; ...Significant baseline differences were education level and CESD [Center for Epidemiologic Studies Depression Scale] score."
Intention-to-treat analysis	Low risk	"All primary and secondary outcomes were analyzed using the intention-to-treat principle."
Groups received same cointerventions	Low risk	No cointerventions were included.

## Sebregts 2005

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Netherlands.</p> <p><b>Dates participants recruited:</b> February 1996 to November 1997.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 8 weeks and 1 year.</p>
Participants	<p><b>Inclusion criteria:</b> aged &lt; 70 years with a confirmed diagnosis of AMI, CABG, or both, and who were able to participate in the regular physiotherapy exercise programme, starting early after discharge</p> <p><b>Exclusion criteria:</b> non-Dutch speaking, illiterate, or experiencing a psychiatric disorder that would severely disturb participation in the intervention</p> <p><b>Indication (% participants):</b> AMI CABG (100%) including: MI only (70.1%), MI + CABG (7.6%), or CABG only (22.4%)</p> <p><b>Psychopathology:</b> major depression, SCID (11.8%) (intervention: 14.9%; comparator: 9.0%)</p> <p><b>Number randomised:</b> total: 204; intervention: 106; comparator: 98.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 55.6 (SD NR) years; intervention: 55.6 <math>\pm</math> 8.0 years; comparator: 55.2 <math>\pm</math> 9.7 years</p> <p><b>Men:</b> total: 86%; intervention: 86%; comparator: 87%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> during the group sessions, participants and their partners (whose participation was encouraged) were informed about coronary risk factors and risk factor modification by a multidisciplinary team. Sessions included didactic teaching and group</p>

	<p>discussion. Each session concluded with breathing and relaxation exercises. Participants were offered an audiotape to use at home to practise breathing and relaxation exercises. Participants were also given homework and written information on course materials</p> <p><b>Treatment targets:</b> risk education, behaviour change, stress, Type A behaviours</p> <p><b>Components:</b> risk education, guidance on behaviour change, relaxation, homework; also some self-awareness/monitoring, client-led discussion</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (6-10 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>• length of session: 2.5 hours;</li><li>• frequency/number of sessions: weekly/8;</li><li>• total duration: 20 contact hours, over 8 weeks.</li></ul> <p><b>Delivered by:</b> psychologist, and either a social worker or a pastor present as cotherapist</p> <p><b>Follow-up further reinforcement:</b> after the last session, 3 follow-up sessions were scheduled at 3, 6, and 9 months, to discuss the achievements that participants had made with respect to risk factor modification</p> <p><b>Cointerventions:</b> usual medical care, including education and exercise programme</p> <p><b>COMPARATOR:</b> usual medical care, consisting of regular cardiologist check-ups, and postdischarge exercise training sessions</p> <p><b>Cointerventions:</b> NR.</p>	
Outcomes	<p>Total mortality.</p> <p>Revascularisation (CABG and PCI).</p> <p>Depression (BDI).</p> <p>Type A behaviour (clinical observation of behaviours).</p> <p>Vital exhaustion (Maastricht Questionnaire).</p>	
Source of funding	Netherlands Heart Foundation (Nederlandse Hartstichting).	
Conflicts of interest	NR.	
Notes		
<b>Risk of bias</b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	<p>“To allocate men and women... a stratified randomization procedure was developed by a person not involved in the study.”</p> <p>“Patients randomised to the intervention group had higher scores on ...BDI depression than the control group.”</p>
Allocation concealment (selection bias)	Low risk	The outcome of the [stratified] randomisation was put in a sealed envelope, and participants received this envelope after the baseline interview

**Sebregts 2005** (Continued)

Blinding of outcome assessment (detection bias)	Low risk	"The interviewers remained unaware of patient groups assignment."
Incomplete outcome data (attrition bias) All outcomes	Low risk	Analysis is intention-to-treat with dropouts reported for both groups
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	High risk	"On average, patients randomised to the intervention group had higher scores on vital exhaustion (P=.05) and BDI depression (P=.07) than did patients in the control group (Table 2)."
Intention-to-treat analysis	Low risk	"Analyses were performed according to the intention-to-treat principle."
Groups received same cointerventions	High risk	Intervention includes structured education around risk reduction not available to comparator group

**Stern 1983**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> USA.</p> <p><b>Dates participants recruited:</b> NR.</p> <p><b>Participants recruited (number of sites):</b> hospital (1) and community referrals (NR).</p> <p><b>Maximum follow-up:</b> 1 year.</p> <p><b>Follow-up schedule:</b> 3 months, 6 months, and 1 year.</p>
Participants	<p><b>Inclusion criteria:</b> aged 30-69 years, with a documented MI within past 6 weeks to 1 year. In addition, eligibility based on 1 or both of the following: work capacity level &lt; 7 (men) or &lt; 6 (women) during treadmill exercising to 85% of the predicted age-adjusted maximum, or appearance of symptoms/abnormal responses causing termination of exercise prior to attaining the heart rate end point; and anxiety (<math>\geq 19</math> Taylor Manifest Anxiety Scale) or depression (<math>\geq 40</math> ZDS)</p> <p><b>Exclusion criteria:</b> people with unstable cardiovascular condition present or required treatment for any physiological or psychological reason</p> <p><b>Indication (% participants):</b> documented MI within past 6 weeks to 1 year (100%).</p> <p><b>Psychopathology:</b> anxiety/depression (43.8%) (intervention: 40.0%; comparator: 48.3%)</p> <p><b>Number randomised:</b> total: 64; intervention: 35; comparator: 29.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: 54 (SD NR) years (range 30-69); intervention: NR; comparator: NR</p> <p><b>Men:</b> total: 83%; intervention: 89%; comparator: 76%.</p> <p><b>Ethnicity (% white):</b> total: 83%; intervention: 80%; comparator: 86%.</p>

Interventions	<p><b>INTERVENTION 'counselling':</b> initial session acquainted people with general problems encountered during convalescence. Sessions 2 and 3 were educational focusing on the aetiology and coronary risk factors. The fourth session examined stress and the role of Type A behaviour. Participants were taught the Jacobsen relaxation exercise and encouraged to do these at least twice daily. Sessions 5-11 were devoted to discussing general areas of stress. The final session was a summary discussion</p> <p><b>Treatment targets:</b> cardiac risk education, behaviour change, stress and Type A behaviour</p> <p><b>Components:</b> risk information, guidance on behaviour change, relaxation training, client-led discussion, homework; also some self-awareness/monitoring</p> <p><b>Treatment setting (number of sites):</b> NR (NR).</p> <p><b>Modality (group size):</b> group (4-6 participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"><li>• length of session: 60-75 minutes;</li><li>• frequency/number of sessions: weekly/12;</li><li>• total duration: 12-15 contact hours, over 12 weeks.</li></ul> <p><b>Delivered by:</b> psychiatrist/social worker and nurse clinician.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> education.</p> <p><b>COMPARATOR:</b> usual medical care, participants were requested not to join an exercise programme or attend counselling</p> <p><b>Cointerventions:</b> NR.</p>		
Outcomes	<p>Total mortality.</p> <p>Non-fatal MI.</p> <p>Revascularisation (CABG).</p> <p>Anxiety (Taylor 1953; data incomplete).</p> <p>Depression (ZDS; data incomplete).</p> <p>Return to work.</p>		
Source of funding	National Institute of Handicapped Research, Department of Education, Washington, DC		
Conflicts of interest	NR.		
Notes			
<i>Risk of bias</i>			
Bias	Authors' judgement	Support for judgement	
Random sequence generation (selection bias)	Unclear risk	Randomly assigned in blocks of 6; no further details provided	
Allocation concealment (selection bias)	Unclear risk	NR.	
Blinding of outcome assessment (detection bias)	Unclear risk	NR.	

**Stern 1983** (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	NR.
Selective reporting (reporting bias)	Low risk	All outcomes described in the methods were reported in the results section
Groups balanced at baseline	High risk	“More controls were in the unmarried category (P <0.03), more exercise patients were in the 49 to 58 year old age range (P <0.02) and more group patients were admitted less than four months following MI (P <0.05).”
Intention-to-treat analysis	Unclear risk	NR.
Groups received same cointerventions	High risk	Intervention included education.

**Turner 2013**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Australia.</p> <p><b>Dates participants recruited:</b> June 2006 to May 2008.</p> <p><b>Participants recruited (number of sites):</b> hospital, adverts, research registers (NR).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 2, 6, and 13 months.</p>
Participants	<p><b>Inclusion criteria:</b> aged <math>\geq 18</math> years; cardiac event <math>\geq 2</math> months prior (ACS, PCI, CABG) or confirmed diagnosis of a heart condition (CHD, congestive heart failure, cardiomyopathy, chronic atrial fibrillation) (or both); and depressive symptoms (<math>&gt; 13</math> BDI-II) at initial screening</p> <p><b>Exclusion criteria:</b> history or current psychotic illness or organic brain diseases at initial screening; antidepressant medication for <math>&lt; 1</math> month's duration, and non-English speakers</p> <p><b>Indication (% participants):</b> past admissions or treatment for ACS, PCI, or CABG (88%); congestive heart failure, chronic atrial fibrillation, or cardiomyopathy (12%)</p> <p><b>Psychopathology:</b> depressive symptoms, <math>&gt; 13</math> BDI-II (100%).</p> <p><b>Number randomised:</b> total: 57; intervention: 25; comparator: 32.</p> <p><b>Age (mean <math>\pm</math> SD):</b> total: <math>62.0 \pm 10.0</math> years; intervention: <math>61.0 \pm 11.0</math> years; comparator: <math>6.20 \pm 9.0</math> years</p> <p><b>Men:</b> total: 72%; intervention: 76%; comparator: 72%.</p> <p><b>Ethnicity (% white):</b> NR.</p>
Interventions	<p><b>INTERVENTION:</b> CBT group intervention following a treatment manual included: emotional distress; activity planning; thought monitoring and challenging; structured problem-solving; strategies to increase motivation; and a programme review and how to get further assistance. Group discussion around experiences and learning from homework tasks, introduction to various skills, and homework was set for the following week</p> <p><b>Treatment targets:</b> reduce depression.</p> <p><b>Components:</b> psychoeducation including emotional distress, activity planning, thought</p>

	<p>monitoring and challenging, structured problem-solving, strategies to increase motivation, and a programme review and how to get further assistance</p> <p><b>Treatment setting (number of sites):</b> community-based programme (NR).</p> <p><b>Modality (group size):</b> group (<math>\leq 11</math> participants).</p> <p><b>Dose:</b></p> <ul style="list-style-type: none"> <li>length of session: 1.5 hours (weeks 2, 3, 4, 5), 2.5 hours (week 1 and 6);</li> <li>frequency/number of sessions: weekly/6;</li> <li>total duration: 11 contact hours, over 6 weeks.</li> </ul> <p><b>Delivered by:</b> clinical psychologists.</p> <p><b>Follow-up further reinforcement:</b> NR.</p> <p><b>Cointerventions:</b> NR.</p> <p><b>COMPARATOR:</b> brief educational intervention feeding back assessment results, providing education, written self-help materials and guidance on support available for mental health. In initial meeting, participants received individualised verbal feedback regarding assessment results (severity of depression and anxiety symptoms, likely presence of a depressive or anxiety disorder, alcohol consumption) and any other concerns. Recommendations for treatment were provided, including: written self-help material on depression, anxiety, and stress, in the context of co-occurring cardiac disease; and relevant mental health and support services information. Individualised letters (and telephone call if symptoms were severe or concerning (or both)) were sent to the participant's selected health professionals (cardiac rehabilitation nurse, general practitioner, specialists) regarding baseline and 2-month assessment results</p> <p><b>Cointerventions:</b> NR.</p>		
Outcomes	<p>Anxiety (HADS-A).</p> <p>Depression (BDI).</p>		
Source of funding	Australian Rotary Health.		
Conflicts of interest	Authors reported no conflict of interest.		
Notes			
<b>Risk of bias</b>			
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>	
Random sequence generation (selection bias)	Low risk	<p>"Once a block of participants was recruited, participants in that block were randomly assigned to receive either an additional six weekly group CBT sessions (CBT) or no further intervention (BI [brief intervention]). A block randomisation procedure was utilised, with a computer-generated random number sequence created by an independent researcher and placed in an opaque envelope. Maximum block size was 11 with smaller size at times of slower recruitment to ensure minimum time be-</p>	

**Turner 2013** (Continued)

		tween assessment and allocation.”
Allocation concealment (selection bias)	Low risk	A block randomisation procedure was utilised, with a computer-generated random number sequence created by an independent researcher and placed in an opaque envelope. Maximum block size was 11 with smaller size at times of slower recruitment to ensure minimum time between assessment and allocation.” “Baseline assessors were informed of condition allocation once all participants in that block had completed their assessment.”
Blinding of outcome assessment (detection bias)	Low risk	“All participants completed follow-up assessments at 2, 6 and 12 months with an assessor blind to treatment allocation.”
Incomplete outcome data (attrition bias) All outcomes	Low risk	Lost to follow-up at 6 and 12 months (including 3 deaths): 17.5% (intervention: 5; comparator: 5)
Selective reporting (reporting bias)	Low risk	All outcomes reported.
Groups balanced at baseline	Low risk	“No significant differences occurred between the CBT ( $n = 25$ ) or BI [brief intervention] conditions ( $n = 32$ ) on any of the baseline characteristics (Table 1).”
Intention-to-treat analysis	Unclear risk	NR.
Groups received same cointerventions	Low risk	“Participants were able to access additional treatments outside the research study and these were monitored during follow-up assessments.”

**Turner 2014**

Methods	<p><b>Design:</b> multicentre RCT.</p> <p><b>Country:</b> Australia.</p> <p><b>Dates participants recruited:</b> March 2007 to November 2008.</p> <p><b>Participants recruited (number of sites):</b> hospital (2).</p> <p><b>Maximum follow-up:</b> 12 months.</p> <p><b>Follow-up schedule:</b> 4 and 12 months.</p>
Participants	<p><b>Inclusion criteria:</b> post-AMI, CABG, or PCI; aged <math>\leq 75</math> years; residing in metropolitan Melbourne; and understood English</p> <p><b>Exclusion criteria:</b> serious physical or psychiatric illness/disability, transport difficulties, non-availability for follow-up</p>

	<i><b>Indication (% participants):</b></i> post-AMI, CABG or PCI (100%); AMI or PCI event (vs CABG) (intervention: 48%; comparator: 76%) <i><b>Psychopathology:</b></i> significant depression symptoms (100%). <i><b>Number randomised:</b></i> total: 42; intervention: 21; comparator: 21. <i><b>Age (mean ± SD):</b></i> total: NR; intervention: 55.6 ± 8.8 years; comparator: 57.0 ± 11.2 years <i><b>Men:</b></i> total: 79%; intervention: 86%; comparator: 71%. <i><b>Ethnicity (% white):</b></i> NR.	
Interventions	<b>INTERVENTION:</b> Beating Heart Problems group programme included 8 modules: physical activity, diet, medication adherence, smoking cessation, depression, anxiety, anger, and social support. Manualised guidelines utilising motivational interviewing and CBT components were followed. Participants received weekly handouts from a group workbook. The intervention was conducted as a rolling group (maximum 9 participants) with participants joining the group the week after randomisation <i><b>Treatment targets:</b></i> reduce/manage depression, anxiety, anger. <i><b>Components:</b></i> motivational interviewing (risk reduction), CBT (depression, anxiety, anger, and social support) <i><b>Treatment setting (number of sites):</b></i> hospital (2). <i><b>Modality (group size):</b></i> group (up to 9 participants). <i><b>Dose:</b></i> <ul style="list-style-type: none"><li>● length of session: NR;</li><li>● frequency/number of sessions: weekly/8;</li><li>● total duration: insufficient information to calculate contact hours, over 8 weeks.</li></ul> <i><b>Delivered by:</b></i> psychologists. <i><b>Follow-up further reinforcement:</b></i> NR. <i><b>Cointerventions:</b></i> NR. <b>COMPARATOR:</b> usual medical care. <i><b>Cointerventions:</b></i> NR.	
Outcomes	Anxiety (HADS-A). Depression (BDI).	
Source of funding	Australian Rotary Health and the Norman H Johns Trust.	
Conflicts of interest	Authors declared no conflict of interest.	
Notes		
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Randomisation not described.
Allocation concealment (selection bias)	Unclear risk	Not described.



**Turner 2014** (Continued)

Blinding of outcome assessment (detection bias)	Low risk	“Four- and 12-month follow-up assessments were conducted with outcome assessors blinded to treatment allocation.”
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	“Of the 42 patients, 11 (26.2%) patients were lost to follow-up by 4 months and 12 (28.6%) by 12 months, with no differences in ICBT [Beating Heart Problems group programme] and control group attrition.”
Selective reporting (reporting bias)	Low risk	All outcomes described in methods were reported for all outcomes
Groups balanced at baseline	Low risk	“At baseline, patients in the ICBT [Beating Heart Problems group programme] group were more likely to be partnered than those in the control group (Table 1). No other baseline differences were found.”
Intention-to-treat analysis	Low risk	“Intention-to-treat analysis was undertaken, with ICBT [Beating Heart Problems group programme] patient retained in their original group, regardless of programme completion.”
Groups received same cointerventions	Low risk	“Control participants received no intervention beyond usual medical care.”

**Van-Dixhoorn 1999**

Methods	<p><b>Design:</b> single-centre RCT.</p> <p><b>Country:</b> Netherlands.</p> <p><b>Dates participants recruited:</b> 1981-1983.</p> <p><b>Participants recruited (number of sites):</b> hospital (1).</p> <p><b>Maximum follow-up:</b> 5 years.</p> <p><b>Follow-up schedule:</b> post-test (~ 6 weeks), 2 and 5 years.</p>
Participants	<p><b>Inclusion criteria:</b> no age limit, diagnosis of recent MI (&lt; 1 month), and the ability to participate in a physical exercise programme</p> <p><b>Exclusion criteria:</b> people considered in need of individual (psychosocial) help in addition to exercise training (from van Dixhoorn 1991).</p> <p><b>Indication (% participants):</b> AMI within 1 month (100%).</p> <p><b>Psychopathology:</b> none (0%).</p> <p><b>Age (mean ± SD):</b> total: 55.5 (SD NR) years; intervention: 55.4 ± 8.2 years; comparator: 55.7 ± 8.1 years</p> <p><b>Men:</b> total: 94%; intervention: 93%; comparator: 95%.</p> <p><b>Ethnicity (% white):</b> NR.</p>

Interventions	<b>INTERVENTION:</b> procedure included: electromyography feedback of the frontalis muscle was used as a “mental device” to focus attention for passive relaxation, to give feedback of muscle tension and explain the concept of relaxation, and to monitor excess inspiratory effort. Participants also learned a method of breathing regulation and the therapist chose the appropriate instructions for each participant. Participants were asked to practise at home <i>Treatment targets:</i> stress. <i>Components:</i> active and passive relaxation, homework. <i>Treatment setting (number of sites):</i> NR (NR). <i>Modality (group size):</i> individual. <i>Dose:</i> <ul style="list-style-type: none"><li>● length of session: 1 hour;</li><li>● frequency/number of sessions: weekly/6;</li><li>● total duration: 6 hours, over 6 weeks.</li></ul> <i>Delivered by:</i> 5 specially trained people including a psychologist, medical doctor, and physiotherapist <i>Follow-up further reinforcement:</i> NR. <i>Cointerventions:</i> physical exercise training (as provided to comparator group) and usual medical care <b>COMPARATOR:</b> physical exercise training and usual medical care. Exercise training was offered as a 5-week programme, once per day for 30 minutes, within groups of 4 participants supervised by 2 physiotherapists <i>Cointerventions:</i> NR.	
Outcomes	Cardiac mortality. Non-fatal MI. Revascularisation. Cost-effectiveness.	
Source of funding	NR.	
Conflicts of interest	NR.	
Notes		
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Reported randomisation, but insufficient detail provided.
Allocation concealment (selection bias)	Unclear risk	Not described.
Blinding of outcome assessment (detection bias)	Unclear risk	Methods stated that clinical data were extracted from medical records, but did not state by whom

Incomplete outcome data (attrition bias) All outcomes	Low risk	All the randomised 156 participants were included in the 2- and 5-year follow-up analyses
Selective reporting (reporting bias)	Unclear risk	Not described.
Groups balanced at baseline	Low risk	“There were no differences between the two treatments in base-line clinical data as shown in <a href="#">Table 1</a> .”
Intention-to-treat analysis	Low risk	“Finally, dropouts were included and classified on the basis of the reason for not completing the programme.”
Groups received same cointerventions	Low risk	Comparator participants received exercise training only, while intervention group participants received exercise training plus relaxation therapy

ACS: acute coronary syndrome; AMI: acute myocardial infarction; ANCOVA: analysis of covariance; BDI: Beck Depression Inventory ([Beck 1997](#)); CABG: coronary artery bypass graft; CAD: coronary artery disease; CBT: cognitive behavioural therapy; CHD: coronary heart disease; CVD: cardiovascular disease; DISH: Depression Interview and Structured Hamilton; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders - 4th edition; ECG: electrocardiograph; HADS-A: Hospital Anxiety and Depression scale - Anxiety subscale ([HADS 1983](#)); HADS-D: Hospital Anxiety and Depression scale - Depression subscale ([HADS 1983](#)); HAM-D: Hamilton Depression Rating Scale ([HAM-D 1988](#)); HRQoL: health-related quality of life; LVEF: left ventricular ejection volume; Maastricht Questionnaire: Maastricht Questionnaire for Vital Exhaustion ([MIVE 1996](#); [MQ 1987](#)); MacNew Questionnaire: MacNew Heart Disease Health-Related Quality of Life Questionnaire ([Lim 1993](#)); MI: myocardial infarction; NR: not reported; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; PHQ-9: Patient Health Questionnaire 9; PSS-10: Perceived Stress Scale 10; PTCA: percutaneous transluminal coronary angioplasty; RCT: randomised controlled trial; SADS-C: Schedule of Affective Disorders and Schizophrenia - Change; SCL-90-R: Symptoms Checklist List - 90 - Revised ([SCL-90-R 1983](#)); SD: standard deviation; SF-12: 12-item Short Form ([Short Form Questionnaires](#)); SF-36: 36-item Short Form ([Short Form Questionnaires](#)); SSM: supportive stress management; STAI: Spielberger Trait Anxiety Inventory ([STAI 1970](#)); STAXI: Spielberger Anger scales ([STAXI 1985](#)); STEMI: ST-elevation myocardial infarction; ZDS: Zung Self-rated Depression Rating Scale ([Zung 1965](#)).

### Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
<a href="#">Agren 2012</a>	Comparator group also received psychological intervention.
<a href="#">Allen 2011</a>	Intervention targeted risk reduction.
<a href="#">Allison 2000</a>	Not a psychological intervention.

(Continued)

Arabia 2011	Comparator group also received psychological intervention.
Bagheri 2007	Follow-up too short (5 months).
Bahrainian 2009	Participants were not randomised.
Bay 2008	Intervention was cardiac rehabilitation including exercise.
Beckie 2006	Ongoing study identified in second update: intervention was multifactorial
Beckie 2011	Intervention was multifactorial.
Beresnevaite 2011	No primary outcomes of interest were collected.
Bettencourt 2005	Exercise-based programme.
Bishop 2005	Follow-up too short and mixed participant group.
Blom 2009	No outcomes of interest were collected.
Blumenthal 2005	Follow-up too short (8 weeks).
Boese 2013	Intervention was peer led (not delivered by a trained practitioner)
Bogner 2016	Population was mixed - while data were analysed separately for heart disease, this subpopulation included heart failure and atrial fibrillation
Boyne 2013	Population had heart failure.
Brodie 2008	Cross-over trial in which comparator participants were offered treatment before the 9-month follow-up
Buckley 2007	No useful outcomes.
Burell 1996b	Not an RCT.
Carson 1988	Follow-up too short (6 weeks).
Chair 2013	Intervention targeted risk reduction.
Chair 2014	Intervention was multifactorial.
Chen 2005	Follow-up too short (12 weeks).
Chung 2014	Population had heart failure.
Clark 2009	Mixed participant group including heart failure and cardiomyopathy

(Continued)

Climov 2014	Follow-up < 6 months.
Cockayne 2014	Population had heart failure.
Copeland 2010	Population had heart failure.
CORE 2000	Ongoing study identified in second update: intervention was exercise
Corones-Watkins 2014	Intervention was educational.
Coventry 2012	Population was mixed - included people with diabetes.
Coventry 2015	Population was mixed - people with depression and CHD or diabetes
Cowan 2001	Population did not have CHD.
Dao 2011	Follow-up < 6 months.
Davidson 2013	Comparator group also received psychological intervention.
de-Klerk 2004	Follow-up too short (5 days).
DeBusk 1994	Not a psychological intervention.
del Pino 2005	Not an RCT.
Di Mario 2010	Review article.
Donohue 2014	Intervention largely pharmacological.
Dunbar 2009	Comparator group also received psychological intervention.
Dusseldorp 1999	Not an RCT.
Erdman 1983	Not a psychological intervention.
Fang 2003	Follow-up too short (8 weeks); unsuitable participant group.
Firestone 2008	Comparator group also received psychological intervention.
Focht 2004	Participants recruited for implantable cardioverter defibrillator
Frasure 2006	Ongoing study identified in second update: follow-up < 6 months
Frasure-Smith 1985	Not a psychological intervention.
Frasure-Smith 1997	Not a psychological intervention.

(Continued)

<a href="#">Fridlund 1991</a>	Intervention included exercise.
<a href="#">Friedman 1986</a>	Not an RCT.
<a href="#">Gallagher 2003</a>	Follow-up too short (3 months).
<a href="#">Gary 2010</a>	Comparator group also received psychological intervention.
<a href="#">Gellis 2014</a>	Intervention was multifactorial.
<a href="#">Giallauria 2009</a>	Intervention was multifactorial.
<a href="#">Giannuzzi 2008</a>	Not a psychological intervention.
<a href="#">Goodman 2008</a>	Follow-up too short (3 months).
<a href="#">Gruen 1975</a>	Follow-up too short (4 months).
<a href="#">Gunnarsdottir 2007</a>	Follow-up too short (3 months).
<a href="#">Gutschker 1982</a>	Included exercise.
<a href="#">Hardcastle 2008</a>	Not a psychological intervention.
<a href="#">Harting 2006</a>	Mixed participant group including heart failure and CHD or 2 risk factors
<a href="#">Hattan 2002</a>	Follow-up too short (4 weeks).
<a href="#">Heisler 2013</a>	Population had heart failure.
<a href="#">Higgins 2001</a>	Interventions delivered by non-psychologically trained clergy
<a href="#">Hofman Bang 1999</a>	Intervention was multifactorial.
<a href="#">Houle 2012</a>	Intervention was multifactorial.
<a href="#">Huang 2011</a>	Population had heart failure.
<a href="#">Huffman 2014</a>	Intervention was multifactorial.
<a href="#">Hwang 2015</a>	Follow-up < 6 months.
<a href="#">Ibrahim 1974</a>	Participants were not randomised.
<a href="#">Irvine 2010</a>	Population did not have CHD.
<a href="#">Izawa 2005</a>	No useful outcomes.

(Continued)

Jaarsma 2008	Not a psychological intervention.
James 2006	No outcomes of interest.
Jiang 2007	Intervention included exercise.
Jiang 2008	Population had heart failure.
Johansen 2003	Follow-up too short (12 weeks).
Johnston 1999	Staff not trained in psychological intervention.
Jolly 1998	Not a psychological intervention.
Kanji 2004	Follow-up too short (6 weeks).
Karlsson 2007	Intervention included exercise.
Kato 2013	Population had heart failure.
King 1988	Not an RCT.
Klein 2007	Follow-up too short (16 weeks).
Konstam 2013	Population had heart failure.
Krucoff 2001	Intervention was not psychological.
Ku 2002	Intervention included many optional components; only 84% of participants selected the stress management component and no separate analyses reported for this group
Kummel 2008	Not a psychological intervention.
Lahmann 2008	Participants recruited with hypertension only. Follow-up too short (4 months)
Lewin 2002	Not a psychological intervention.
Lewin 2009	Participants recruited for non-specific chest pain.
Lidell 1996	Intervention included exercise.
Liljeroos 2012	Population had heart failure.
Lima 2010	Intervention was not psychological.
Luszczynska 2006	No useful outcomes.

(Continued)

Luszczynska 2007	No useful outcomes.
MacIntyre 2008	Intervention delivered by nurses, but no mention of psychological training
Mandel 2007	Mixed participant group including heart failure and stroke.
Mandel 2008	Mixed participant group including arrhythmia, heart failure, and valvular disease
Maroto Montero 2005	Intervention delivered by cardiac nurses without specific training
McGillion 2008	Follow-up too short (5 months).
McHugh 2001	Staff not trained in psychological intervention.
Meister 2013	Comparator group also received psychological intervention.
Meyer 2014	Intervention largely pharmacological.
Mitsibounas 1992	No relevant outcomes.
Mittag 2006	Intervention was multifactorial.
Mohiuddin 2007	Not a psychological intervention.
Moser 2012	Population had heart failure.
Moulaert 2013	Intervention was multifactorial.
Mulligan 2008	Population had heart failure.
Nordmann 2001	Not a psychological intervention.
Novoa 2008	Follow-up too short (4 months).
Nyklicek 2014	Comparator group also received psychological intervention.
Oldenburg 1995	Intervention included exercise.
Oldridge 1995	Intervention included exercise.
Ornish 1990	Intervention included exercise.
Ornish 1998	Intervention included exercise.
Orth-Gomer 2009	Intervention was multifactorial.
Parent 2000	Follow-up too short (16 weeks).



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Paul 2006	Follow-up too short (12 weeks).
Petrie 2002	Follow-up too short (immediate postintervention).
PRECOR Group 1991	Not a psychological intervention.
Price 2004	Not an RCT.
Pullen 2008	Not an RCT (case-matched historical controls).
Quist-Paulson 2003	Intervention is for smoking cessation.
Reid 2003	Not a psychological intervention; treatment included exercise
Robert-McComb 2004	Follow-up too short (10 weeks).
Rollman 2011	Intervention largely pharmacological.
Russell 2013	Comparator group also received psychological intervention.
Salminen 2005	Did not state whether staff were psychologically trained.
Salmoirago-Blotcher 2013	Population did not have CHD.
Scholz 2006a	Intervention targets physical activity.
Scholz 2006b	Not a psychological intervention; treatment included exercise
Seekatz 2013	Participants were not randomised.
Senuzun 2006	Follow-up too short (2 months) and no suitable outcomes.
Seskevich 2004	Follow-up too short (4 months).
Shemesh 2011	Follow-up less than 6 months.
Sheps 2004	Not an RCT.
Shively 2011	Population had heart failure.
Sinclair 2005	Exercise-based programme.
Sniehotta 2006	Follow-up too short (1 month).
Sogolitsapneh 2009	Participants were not randomised.
Stein 2010	Intervention was an audiotape - no therapist input.

(Continued)

Stenlund 2005	No useful outcomes.
Taghadosi 2014	Population had heart failure.
Thompson 1989	Staff not trained in psychological intervention.
Toobert 1998	Intervention included exercise.
Tyrer 2014	Population was mixed.
van Dixhoorn 1991	Not an RCT.
van Dixhoorn, 1983	Follow-up period not stated, but seems likely < 6 months. Authors contacted for clarification with no reply
van Elderen 2001	No mention of randomisation.
Vatutin 2013	Population had heart failure.
Vermeulen 1983	Intervention included exercise.
Vestfold Heartcare Study Group 2003	Not a psychological intervention; treatment included exercise
Wan 2005	Follow-up too short (8 weeks).
Wensaas 2014	Intervention targeted risk reduction.
Wyer 2001	No useful outcomes.
Xue 2008	Participants at risk of CHD, but without established disease
Yari 2011	Population had heart failure.
Yeh 2008	Not a psychological intervention.
Yu 2014	Population had heart failure.
Zeng 2001	Follow-up too short.
Zetta 2011	Intervention was multifactorial.
Zhu 2006	Staff administering psychological intervention did not receive specialist training
Zuidersma 2013	Intervention was multifactorial.

CHD: coronary heart disease; RCT: randomised controlled trial.

## Characteristics of studies awaiting assessment *[ordered by study ID]*

### Ma 2010

Methods	Unknown.
Participants	People with coronary heart disease after a percutaneous transluminal coronary angioplasty
Interventions	'Psychological intervention.'
Outcomes	Unknown.
Notes	Published in Chinese. Only abstract available - awaiting full text for translation

## Characteristics of ongoing studies *[ordered by study ID]*

### Albus 2014

Trial name or title	A Stepwise Psychotherapy Intervention for Reducing Risk in Coronary Artery Disease (SPIRR-CAD): Rationale and Design of a Multicenter, Randomised Trial in Depressed Patients with CAD
Methods	RCT.
Participants	450 participants with any manifestation of CAD and depression scores $\geq 8$ on HADS-D
Interventions	<b>Intervention:</b> 3 initial sessions of supportive individual psychotherapy, after re-evaluation of depression (weeks 4-8), participants with persisting symptoms receive an additional 25 sessions of combined psychodynamic and group CBT <b>Comparator:</b> participants receive 1 psychosocial counselling session.
Outcomes	Cardiac events. Depression (HADS-D, HAM-D). HRQoL (SF-36). Cost-effectiveness up to 24 months of follow-up.
Starting date	Participant recruited November 2008-2011.
Contact information	C Albus, Dept of Psychosomatic Medicine, University of Cologne, Kerpener Str 62; D-50931 Koeln, Cologne, Germany. E-mail address: christian.albus@uk-koeln.de
Notes	Conference abstract of initial findings: Deter HC, Orth-Gomer K, Herrmann-Lingen CH, Albus CH, Boese A, Juenger J, et al. (2014). Psychosocial gender differences in CAD and effect of a psychosocial intervention on vital exhaustion findings from the SPIRR-CAD trial. European Heart Journal 35: 225

### Barley 2014

Trial name or title	The UPBEAT Nurse-Delivered Personalized Care Intervention for People with CHD who Report Current Chest Pain and Depression: a Randomised Controlled Pilot Study
Methods	RCT.
Participants	81 participants with CHD scoring $\geq 3$ PHQ-2, reported current chest pain and $\geq 8$ on HADS-D subscale
Interventions	<b>Intervention:</b> 6-month personalised care plan including case management and regular telephone review <b>Comparator:</b> usual general practice care.
Outcomes	Anxiety (HADS-A). Depression (HADS-D). HRQoL (Modified Rose Angina Questionnaire, SF-12).
Starting date	Participants recruited October 2010 to June 2011.
Contact information	E Barley, Florence Nightingale School of Nursing and Midwifery, James Clerk Maxwell Building, King's College London, London, UK. E-mail: elizabeth.barley@kcl.ac.uk
Notes	

### Eckert 2010

Trial name or title	Detection and Management of Depression in Patients with Chronic Heart Disease: The Take Heart in Primary Care Cluster Randomised Controlled Trial
Methods	RCT.
Participants	282 participants: 78% CAD; 45% chronic angina pectoris; 37% AMI, 36% AF and 20% HF. At baseline, 24% intervention and 32% comparator were depressed
Interventions	<b>TAKE HEART intervention:</b> screening for depression, academic detailing and tailored psychiatric advice <b>Comparator:</b> usual primary care management.
Outcomes	Depression (CES-D scale).
Starting date	Not reported.
Contact information	K Eckert, University of Adelaide, Hanson Institute, Adelaide, Australia
Notes	Data extracted from conference abstract only.

### Norlund 2015

Trial name or title	Treatment of Depression and Anxiety with Internet-Based Cognitive Behavior Therapy in Patients with a Recent Myocardial Infarction (U-CARE Heart): Study Protocol for a Randomised Controlled Trial
Methods	RCT.
Participants	500 participants with AMI, with depression or anxiety (or both) score of > 7 on HADS-A or HADS-D subscales
Interventions	<b>Intervention:</b> 14-week internet-based CBT intervention. Participants choose 2 or 3 modules out of 10 modules <b>Comparator:</b> usual care.
Outcomes	Anxiety (HADS-A, Cardiac Anxiety Questionnaire). Depression (HADS-D, Montgomery-Åsberg Depression Rating Scale-Self rating) HRQoL (EQ-5D). Cantril Ladder of Life scale. Everyday Life Stress Scale. Vital exhaustion (Maastricht Questionnaire). Posttraumatic Stress Disorder Checklist - Civilian Version. Posttraumatic Growth Inventory - Short Form.
Starting date	Participant recruitment commenced September 2013.
Contact information	F Norlund, Department of Public Health and Caring Sciences, Uppsala University, Box 564, Uppsala SE-751 22, Sweden. E-mail: fredrika.norlund@pubcare.uu.se
Notes	

### Richards 2016

Trial name or title	Assessing the Effectiveness of Enhanced Psychological Care for Patients with Depressive Symptoms Attending Cardiac Rehabilitation Compared with Treatment as Usual (CADENCE): Study Protocol for a Pilot Cluster Randomised Controlled Trial
Methods	Cluster RCT.
Participants	Up to 64 participants (recruited from 8 cardiac rehabilitation teams) admitted for an ACS or following a coronary revascularisation procedure, with or without HF, and with a new-onset episode of depression (PHQ-9 ≥ 10 score)
Interventions	<b>Enhanced psychological care intervention:</b> embedded into routine cardiac rehabilitation programme lasting approximately 8 weeks. A cardiac nurse specialist will implement within the rehabilitation programme. Enhanced psychological care includes: mental healthcare coordination, behavioural activation programme and self-help materials, general practitioner referral, referral to local Improving Access to Psychological Therapies services, or referral to specific cardiac patient psychological support services where available, or a combination <b>Comparator:</b> usual cardiac rehabilitation programme.

**Richards 2016** (Continued)

Outcomes	Total mortality. Cardiac mortality. Cardiac events (ACS and revascularisation procedures). Depression (Becks Depression Inventory). Anxiety (Beck Anxiety Inventory). Behavioral Activation for Depression Scale. HRQoL (EQ-5D and HeartQoL).
Starting date	1 April 2014.
Contact information	S Richards: University of Exeter Medical School, St Luke's Campus, Exeter, EX1 2LU, UK. E-mail: s.h.richards@exeter.ac.uk
Notes	

**Spatola 2014**

Trial name or title	The ACTonHEART Study: Rationale and Design of a Randomised Controlled Clinical Trial Comparing a Brief Intervention Based on Acceptance and Commitment Therapy to Usual Secondary Prevention Care of Coronary Heart Disease
Methods	RCT.
Participants	168 participants recently having AMI, ACS, surgical revascularisation (CABG)
Interventions	<b>Intervention:</b> 5 × 90-minute group sessions over 6 weeks based on Acceptance and Commitment Therapy (ACT) with the aim of positively modifying health-related behaviours and improving psychological health <b>Comparator:</b> usual outpatient cardiac rehabilitation care.
Outcomes	HRQoL (SF-36). Psychological General Well-Being Index.
Starting date	Not reported.
Contact information	C Spatola, Istituto Auxologico Italiano IRCCS, Psychology Research Laboratory, Milan, Italy/Department of Psychology, Catholic University of Milan, Milan, Italy. E-mail: c.spatola@auxologico.it
Notes	

**Tully 2016**

Trial name or title	Cardiovascular Health in Anxiety or Mood Problems Study (CHAMPS): Study Protocol for a Randomized Controlled Trial
Methods	RCT.

Participants	Aged $\geq 18$ years, primary hospital admission for cardiovascular disease, an International Neuropsychiatric Interview diagnosis of major depression, dysthymia, GAD, panic disorder, agoraphobia, social anxiety/phobia, or post-traumatic stress disorder, PHQ-9 $\geq 10$ score or GAD $\geq 7$ score, fluent in English
Interventions	<p><b>Unified protocol intervention:</b> lasting 12-18 weeks, aimed at enhancing motivation, readiness for change, and treatment engagement; psychoeducation about emotions; increasing present focused emotion awareness; increasing cognitive flexibility; identifying and preventing patterns of emotion avoidance and maladaptive emotion-driven behaviours (including tobacco smoking and alcohol use); increasing tolerance of emotion-related physical sensations; interoceptive and situation-based emotion-focused exposure; and relapse prevention strategies</p> <p><b>Comparator:</b> enhanced usual care including an education package delivered by the study coordinator consisting of beyondblue™ fact sheet regarding anxiety, depression, and CHD</p>
Outcomes	<p>Major adverse coronary events.</p> <p>Anxiety severity (GAD-7 and OASIS).</p> <p>Depression (PHQ-9).</p> <p>HRQoL (SF-12).</p> <p>General stress (DASS21).</p>
Starting date	Not stated but “currently recruiting” - paper accepted December 2015
Contact information	P Tully. Freemasons Foundation Centre for Men’s Health, Discipline of Medicine, School of Medicine, The University of Adelaide, Adelaide, Australia. E-mail: phillip.tully@adelaide.edu.au
Notes	

ACS: acute coronary syndrome; AF: atrial fibrillation; AMI: acute myocardial infarction; CABG: coronary artery bypass graft; CAD: coronary artery disease; CBT: cognitive behavioural therapy; CES-D: Center for Epidemiologic Studies Depression Scale; CHD: coronary heart disease; DASS21: Depression Anxiety Stress Scales - 21; GAD: generalised anxiety disorder; HADS-A: Hospital Anxiety and Depression scale - Anxiety subscale ([HADS 1983](#)); HADS-D: Hospital Anxiety and Depression scale - Depression subscale ([HADS 1983](#)); HAM-D: Hamilton Depression Rating Scale ([HAM-D 1988](#)); HR: heart rate; HRQoL: health-related quality of life; MI: myocardial infarction; OASIS: Overall Anxiety Severity and Impairment Scale; PHQ-9: Patient Health Questionnaire 9; RCT: randomised controlled trial; SF-12: 12-item Short Form ([Short Form Questionnaires](#)); SF-36: 36-item Short Form ([Short Form Questionnaires](#)).

## DATA AND ANALYSES

### Comparison 1. Psychological intervention (alone or with other rehabilitation) versus comparator (usual care or other rehabilitation)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Total mortality	23	7776	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.77, 1.05]
2 Cardiac mortality	11	4792	Risk Ratio (M-H, Random, 95% CI)	0.79 [0.63, 0.98]
3 Revascularisation (coronary artery bypass graft surgery and percutaneous coronary intervention combined)	13	6822	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.81, 1.11]
4 Non-fatal myocardial infarction	13	7845	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.64, 1.05]
5 Depression	19	5825	Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.39, -0.15]
6 Anxiety	12	3161	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-0.38, -0.09]
7 Stress	8	1251	Std. Mean Difference (IV, Random, 95% CI)	-0.56 [-0.88, -0.24]

## ADDITIONAL TABLES

Table 1. Other psychological outcomes

Trial	Follow-up (months)	Measure	Scores at follow-up: intervention vs comparator, P value	Between-group difference
<b>Depression</b>				
<a href="#">Appels 2005</a>	18	Depression (clinical diagnosis, DSM-IV criteria)	Odds of being depressed, controlling for age, gender, and baseline depression OR 0.50 (95% CI 0.26 to 0.95), P = 0.04	Intervention > comparator
<a href="#">Freedland 2009</a>	9	Beck Depression Inventory	Mean (SD): CBT 6.7 (8.32) ; SSM 9.9 (9.07) vs 12.9 (9.29), P < 0.001	Intervention > comparator
<a href="#">Mayou 2002</a>	12	Hamilton Anxiety and Depression Combined Score	Median (IQR): 6 (2 to 9) vs 7 (4 to 11.5); mean difference -2.35 (SD NR), P = NS	Intervention comparator
<a href="#">O'Neil 2015</a>	6	Patient Health Questionnaire - 9	Mean (SD): 6.1 (5.5) vs 8.1 (5.8), P = NS	Intervention comparator



**Table 1. Other psychological outcomes** (Continued)

Oranta 2010	18	Beck Depression Inventory (diagnosis)	OR 0.31 (95% CI 0.16 to 0.61) vs 1.15 (95% CI 0.60 to 0.22), P = 0.009	Intervention > comparator
<b>Distress</b>				
Oranta 2010	18	Symptom Checklist-25	OR 0.4 (95% CI 0.21 to 0.84) vs 0.9 (95% CI 0.43 to 1.86), P = NS	Intervention comparator
<b>Anger</b>				
Michalsen 2005	12	Anger (STAXI): State	Mean (SD): 10.9 (2.3) vs 11.1 (2.6), P = NS	Intervention comparator
	12	Anger (STAXI): Trait	Mean (SD): 17.4 (4.2) vs 18 (4.8), P = NS	Intervention comparator
	12	Anger (STAXI): In	Mean (SD): 17.1 (4.7) vs 16.8 (4.9), P = NS	Intervention comparator
	12	Anger (STAXI): Out	Mean (SD): 11.6 (2.7) vs 11.5 (3.1), P = NS	Intervention comparator
	12	Anger (STAXI): Control	Mean (SD): 24.5 (4.2) vs 24.4 (4.5), P = NS	Intervention comparator
<b>Type A behaviour</b>				
Friedman 1982	54	Type A: Videotaped Clinical Interview for Type A behaviour	Mean (SD): 15.5 (8.9) vs 22.1 (9.7), P < 0.001	Intervention > comparator
Sebregts 2005	9	Type A: Revised Videotaped Structured Interview (Hostility subscale)	Mean (SD): 53.6 (25.3) vs 58.9 (29.5), P = 0.03	Intervention > comparator
	9	Type A: Revised Videotaped Structured Interview (Time Urgency subscale)	Mean (SD): 66.5 (29.6) vs 75 (32.1), P = 0.01	Intervention > comparator
	9	Type A: Revised Videotaped Structured Interview (Insecurity subscale)	Mean (SD): 25.8 (20.6) vs 26.3 (22.6), P = NS	Intervention comparator
<b>Vital exhaustion</b>				
Sebregts 2005	9	Maastricht Questionnaire	Mean (SD): 4.6 (5.7) vs 4.7 (5.5), P = NS	Intervention comparator

**Table 1. Other psychological outcomes** (Continued)

Claesson 2005	12		Mean (SD): 12.2 (17.3) vs 15.8 (19.4), $P < 0.05$	Intervention > comparator
Koertge 2008	30		Mean (SD): 16.5 (11.1) vs 16.9 (11.3), $P = 0.005$	Intervention > comparator <sup>a</sup>
Roncella 2013	23		Mean (SD): 56.5 (8.1) vs 59.7 (14.5), $P = NS$	Intervention comparator
<b>Hopelessness</b>				
Freedland 2009	9	Beck Hopelessness Scale	Mean (SD): CBT 3.5 (5.1); SSM 5.5 (5.8) vs 7.5 (6.0), $P = NS$	Intervention comparator

<sup>a</sup> The authors noted in their discussion that “due to regression towards the mean we cannot attribute the decrease in vital exhaustion to the intervention.”

CBT: cognitive behavioural therapy; CI: confidence interval; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders - 4th edition; IQR: interquartile range; OR: odds ratio; NR: not reported; NS: non-significant ( $P > 0.10$ ); SD: standard deviation; SSM: supportive stress management; STAXI: Spielberger Anger scales (STAXI 1985).

**Table 2. Health-related quality of life (HRQoL) scores**

Trial	Follow-up (months)	Measure	Scores at follow-up (mean (SD)): intervention vs comparator, $P$ value	Between-group difference <sup>a</sup>
Appels 2005	18	MacNew Questionnaire: Global Score	126.9 (27.4) vs 127.1 (25.8), $P = NS$	Intervention comparator
Claesson 2005	12	Swedish Quality of Life Scale	6.59 (2.95) vs 5.97 (3.15), $P = NS$	Intervention comparator
ENRICH Investigators 2000	6	SF-12: Physical Component Score	0.8 (23.0), $P = NS^b$	Intervention comparator
	6	SF-12: Mental Component Score	2.2 (18.3), $P < 0.05^b$	Intervention > comparator
	6	Life Satisfaction Scale	1.0 (9.8), $P < 0.05^b$	Intervention > comparator
	6	Ladder of Life	0.3 (4.6), $P < 0.05^b$	Intervention > comparator

**Table 2. Health-related quality of life (HRQoL) scores** (Continued)

Freedland 2009	9	SF-36: Physical Component Score	CBT 37.6 (9.6); SSM 38.9 (9.7) vs 36.9 (10.6), P = NS	Intervention comparator
	9	SF-36 Mental Component Score	CBT 49.1 (12.2); SSM 47.8 (13.0) vs 42.4 (13.3), P = 0.01	Intervention > comparator
Lie 2007	6	SAQ: Physical Limitations	86.4 (15.6) vs 83.2 (18.7), P = NS	Intervention comparator
	6	SAQ: Angina Frequency	91.7 (16.6) vs 90.8 (18.9), P = NS	Intervention comparator
	6	SAQ: Treatment Satisfaction	89.2 (15.4) vs 88.0 (16.1), P = NS	Intervention comparator
	6	SAQ: Disease Perception	77.8 (20.2) vs 3.9 (24.2), P = NS	Intervention comparator
	6	SF-36: Physical Component Score	47.4 (9.6) vs 47.0 (10.0), P = NS	Intervention comparator
	6	SF-36: Mental Component Score	52.1 (10.7) vs 50.5 (10.8), P = NS	Intervention comparator
Mayou 2002	12	Dartmouth COOP	14 (IQR 13 to 17) vs 15 (IQR 12.5 to 21), P = NS <sup>c</sup>	Intervention comparator
Michalsen 2005	12	SF-36: Physical Component Score	43.2 (9.2) vs 46.1 (9.3), P = NS	Intervention comparator
	12	SF-36: Mental Component Score	47.2 (9.2) vs 49.3 (10), P = NS	Intervention comparator
O'Neil 2015	12	SF-12: Physical Component Score	36.6 (10.5) vs 36.2 (10.5), P = NR	Intervention comparator
	12	SF-12: Mental Component Score	45.6 (9.3) vs 42.7 (11.1), P = NR	Intervention comparator
Rakowska 2015	30	SF-36: Physical Component Score	64.3 (5.2) vs 61.7 (4.8), P = 0.04	Intervention > comparator
	30	SF-36: Mental Component Score	58.9 (5.9) vs 53.0 (2.2), P < 0.01	Intervention > comparator

**Table 2. Health-related quality of life (HRQoL) scores** (Continued)

Roncella 2013	12	MacNew Questionnaire: Global Score	6.07 (IQR 5.48 to 6.39) vs 5.67 (IQR 4.89 to 6.31), P = 0.07 <sup>c</sup>	Intervention comparator
	12	MacNew Questionnaire: Emotional Score	5.79 (IQR 5.36 to 6.35) vs 5.79 (IQR 5.0 to 6.32), P = NS <sup>c</sup>	Intervention comparator
	12	MacNew Questionnaire: Physical Score	6.23 (IQR 5.70 to 6.53) vs 5.69 (IQR 4.85 to 6.29), P = 0.03 <sup>c</sup>	Intervention > comparator
	12	MacNew Questionnaire: Social Score	6.15 (IQR 5.69 to 6.61) vs 5.86 (IQR 5.0 to 6.46), P = 0.06 <sup>c</sup>	Intervention comparator

<sup>a</sup> Intervention comparator (intervention and comparator equivalent); intervention > comparator (intervention superior to comparator group).

<sup>b</sup> Mean difference (SD).

<sup>c</sup> Median (IQR) and P value from Mann Whitney U test.

CBT: cognitive behavioural therapy; NS: non-significant (P > 0.10); SAQ: Seattle Angina Questionnaire; SD: standard deviation; SF-12: 12-item Short Form; SF-36: 36-item Short Form; SSM: supportive stress management.

**Table 3. Total mortality: univariate meta-regression results**

Predictor	Total mortality exp(β) (SE)	Explanatory variable coding <sup>a</sup>
Population targeted at baseline		
Psychological disorder present	1.19 (0.18), P = 0.26	Non-selected 0, present 1
<i>Characteristics of psychological intervention</i>		
Mode of treatment	1.21 (0.18), P = 0.21	Individual 0, group 1, both 2
Family included	1.11 (0.19), P = 0.55	No 0, yes 1
CRF education included	0.92 (0.14), P = 0.58	No 0, yes 1
Intervention targeted behavioural change of CRFs	1.06 (0.16), P = 0.72	No 0, yes 1
<i>Psychological treatment targets</i>		
Depression	1.28 (0.25), P = 0.22	No 0, yes 1

**Table 3. Total mortality: univariate meta-regression results** (Continued)

Anxiety	1.22 (0.23), P = 0.31	No 0, yes 1
Stress	1.28 (0.39), P = 0.43	No 0, yes 1
Type A behaviour	0.98 (0.15), P = 0.89	No 0, yes 1
<i>Psychological components</i>		
Relaxation training	1.15 (0.22), P = 0.47	No 0, yes 1
Stress management techniques	1.15 (0.25), P = 0.54	No 0, yes 1
Cognitive challenge/restructuring techniques	1.10 (0.17), P = 0.53	No 0, yes 1
Emotional support or client-led discussion, or both	1.42 (0.25), P = 0.07	No 0, yes 1
Adjunct pharmacology	2.08 (2.53), P = 0.56	No 0, yes 1

<sup>a</sup> If relevant information was not reported the study was coded as 0.  
CRF: cardiac risk factor; SE: standard error.

**Table 4. Cardiac mortality: univariate meta-regression results**

Predictor	Cardiac-mortality $\exp(\beta)$ (SE)	Explanatory variable coding <sup>a</sup>
Population targeted at baseline		
Psychological disorder present	1.17 (0.30), P = 0.58	Non-selected 0, present 1
<i>Characteristics of psychological intervention</i>		
Mode of treatment	1.19 (0.32), P = 0.56	Individual 0, group 1, both 2
Family included <sup>b</sup>	0.82 (0.09), P = 0.13	No 0, yes 1
CRF education included	0.84 (0.24), P = 0.57	No 0, yes 1
Intervention targeted behavioural change of CRFs	1.17 (0.49), P = 0.72	No 0, yes 1
<i>Psychological treatment targets</i>		
Depression	1.13 (0.31), P = 0.67	No 0, yes 1

**Table 4. Cardiac mortality: univariate meta-regression results** (Continued)

Anxiety	1.13 (0.31), P = 0.67	No 0, yes 1
Stress	1.24 (0.71), P = 0.72	No 0, yes 1
Type A behaviour	1.02 (0.46), P = 0.95	No 0, yes 1
<i>Psychological components</i>		
Relaxation training	1.27 (0.74), P = 0.70	No 0, yes 1
Stress management techniques	1.03 (0.46), P = 0.95	No 0, yes 1
Cognitive challenge/restructuring techniques	1.11 (0.40), P = 0.78	No 0, yes 1
Emotional support or client-led discussion, or both	1.16 (0.30), P = 0.58	No 0, yes 1
Adjunct pharmacology <sup>b</sup>	0.82 (0.9), P = 0.13	No 0, yes 1

<sup>a</sup> If relevant information was not reported the variable/study was coded as 0.

<sup>b</sup> 'Yes' category (coded 1) contained no participants. Data reported from a model including 'no' (coded 0) only.

CRF: cardiac risk factor; SE: standard error.

**Table 5. Depression: univariate meta-regression results**

Predictor	Depression exp( $\beta$ ) (SE)	Explanatory variable coding <sup>a</sup>
Population targeted at baseline		
Psychological disorder present	-0.20 (0.12), P = 0.10	Non-selected 0, present 1
<i>Characteristics of psychological intervention</i>		
Mode of treatment	0.007 (0.09), P = 0.94	Individual 0, group 1, both 2
Family included	0.06 (0.14), P = 0.70	No 0, yes 1
CRF education included	0.06 (0.13), P = 0.65	No 0, yes 1
Intervention targeted behavioural change of CRFs	-0.16 (0.12), P = 0.20	No 0, yes 1
<i>Psychological treatment targets</i>		

**Table 5. Depression: univariate meta-regression results** (Continued)

Depression	0.15 (0.13), P = 0.26	No 0, yes 1
Anxiety	0.18 (0.12), P = 0.17	No 0, yes 1
Stress	0.13 (0.13), P = 0.35	No 0, yes 1
Type A behaviour	-0.65 (0.14), P = 0.65	No 0, yes 1
<i>Psychological components</i>		
Relaxation training	-0.09 (0.13), P = 0.50	No 0, yes 1
Stress management techniques	0.09 (0.13), P = 0.52	No 0, yes 1
Cognitive challenge/restructuring techniques	0.07 (0.14), P = 0.59	No 0, yes 1
Emotional support or client-led discussion, or both	0.14 (0.13), P = 0.28	No 0, yes 1
Adjunct pharmacology	-0.51 (0.15), P = 0.003	No 0, yes 1

<sup>a</sup> If relevant information was not reported the variable/study was coded as 0.

CRF: cardiac risk factor; SE: standard error.

**Table 6. Anxiety: univariate meta-regression results**

Predictor	Anxiety exp( $\beta$ ) (SE) P value	Explanatory variable coding <sup>a</sup>
Population targeted at baseline		
Psychological disorder present	-0.28 (0.11), P = 0.03	Non-selected 0, present 1
<i>Characteristics of psychological intervention</i>		
Mode of treatment	0.09 (0.09), P = 0.30	Individual 0, group 1, both 2
Family included	0.24 (0.12), P = 0.06	No 0, yes 1
CRF education included	0.18 (0.13), P = 0.21	No 0, yes 1
Intervention targeted behavioural change of CRFs	-0.08 (0.17), P = 0.61	No 0, yes 1
<i>Psychological treatment targets</i>		

**Table 6. Anxiety: univariate meta-regression results** (Continued)

Depression	-0.04 (0.16), P = 0.83	No 0, yes 1
Anxiety	0.05 (0.15), P = 0.78	No 0, yes 1
Stress	0.18 (0.13), P = 0.20	No 0, yes 1
Type A behaviour	-0.01 (0.26), P = 0.97	No 0, yes 1
<i>Psychological components</i>		
Relaxation training	0.15 (0.14), P = 0.29	No 0, yes 1
Stress management techniques	-0.03 (0.15), P = 0.87	No 0, yes 1
Cognitive challenge/restructuring techniques	-0.16 (0.14), P = 0.29	No 0, yes 1
Emotional support or client-led discussion, or both	0.12 (0.14), P = 0.44	No 0, yes 1
Adjunct pharmacology	-0.12 (0.24), P = 0.65	No 0, yes 1

<sup>a</sup> If relevant information was not reported the variable/study was coded as 0.

CRF: cardiac risk factor; SE: standard error.

## WHAT'S NEW

Date	Event	Description
6 May 2016	New search has been performed	Searches rerun on 27 April 2016 and the results from this new search were subsequently incorporated into the review (14 included studies added (2577 participants))
9 February 2016	New citation required and conclusions have changed	Cardiac rehabilitation services are offering care to more varied populations of people with cardiac conditions (e.g. people with heart failure or arrhythmias). Building on the inclusion criteria proposed by <a href="#">Whalley 2011</a> , this third update now includes trials evaluating psychological interventions recruiting cardiac populations where 50% or more of the patient population has an acute coronary syndrome or angina More recent studies are also seeking to test psychological interventions in comorbid populations (i.e. people with depression, and either acute coronary syndrome or dia-



(Continued)

		<p>betes). These studies were deemed eligible for inclusion as long as the outcome data were reported separately and could be extracted for the subgroup of people with heart disease</p> <p>For the first time, we reported meta-analysis of the effect of psychological interventions on participant-reported stress levels, and the findings from studies reporting participants' levels of return to work, or data on economic evaluations conducted alongside trials. We also included a GRADE assessment of the quality of evidence for each of the primary outcomes</p> <p>We have narrowed the scope of the meta-regression analysis by limiting our investigation to a smaller number of key parameters compared with those explored in the second update</p> <p>The conclusions of this review are essentially unchanged from <a href="#">Whalley 2011</a>, although the precision with which the estimates of effects are derived from clinical and participant-reported outcomes (depression, anxiety) has altered through the addition of new data. We also presented new information from a meta-analysis for the outcome of stress. The findings from the meta-regression have altered in this update</p>
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## HISTORY

Date	Event	Description
7 June 2011	New search has been performed	In addition to updating the original Cochrane review, this update review has restricted inclusion to studies in which: (1) it was stated that staff delivering the psychological intervention had received training in psychological intervention; and (2) that compared the effect of psychological therapy separately from the effects of other non-psychological interventions, particularly exercise training. It has also: (3) introduced a system of classification for psychological interventions based on the aims and components of each treatment; and (4) formally explored the heterogeneity and variation in psychological intervention effects using meta-regression. Finally, (5) the updated review did not consider modifiable cardiac risk outcomes (e.g. serum lipids, blood pressure, or smoking prevalence)

(Continued)

7 June 2011	New citation required but conclusions have not changed	The conclusion of this review remain essentially the same as the previous version of the review i.e. whilst psychological treatments (compared to usual care) appear effective in treating psychological symptoms of participants with coronary heart disease, there no strong evidence of reducing total deaths or risk of revascularisation or non-fatal myocardial infarction in this population
21 August 2008	Amended	Converted to new review format.

## CONTRIBUTIONS OF AUTHORS

SR: study selection, data extraction, risk of bias assessment and analyses, led the writing of the updated review, and approved the final manuscript.

LA: study selection, data extraction, risk of bias assessment and analyses, and edited and approved the final manuscript.

CJ: study selection, data extraction, risk of bias assessment, and edited and approved the final manuscript.

BW: wrote the previous version of this review, advised with study selection and analyses, provided clinical advice, and edited and approved the final manuscript. BW was the lead author on the second version (2011) of this Cochrane review.

KR: edited and approved the final manuscript. KR was the lead author on the first version (2004) of this Cochrane Review, and a co-author on the second version (2011).

PD: edited and approved the final manuscript. PD was a co-author on the second version (2011) of this Cochrane Review.

PB: edited and approved the final manuscript. PB was a co-author on both the first version (2004) and second version (2011) of this Cochrane Review.

ZL: edited and approved the final manuscript. ZL was a co-author on the second version (2011) of this Cochrane Review.

RW: edited and approved the final manuscript. RW was a co-author on both the first version (2004) and second version (2011) of this Cochrane Review.

DRT: edited and approved the final manuscript. DRT was a co-author on the second version (2011) of this Cochrane Review.

RST: advised on study selection, data extraction, risk of bias assessment, and analyses, and edited and approved the final manuscript. RST was a co-author on the second version (2011) of this Cochrane Review.

## DECLARATIONS OF INTEREST

SR is currently a coinvestigator on the CADENCE study (funded by the UK NIHR HTA 12/189/06). This study is a feasibility and pilot study aimed at developing enhanced psychological care for people with new-onset depression using cardiac rehabilitation services (ISRCTN34701576).

LA is an author on several other Cochrane cardiac rehabilitation reviews.

CJ declares she has no conflicts of interest.

KR, PB, and RW were authors of the first version (2004) of this Cochrane Review.

BW, KR, PD, PB, ZL, RW, DRT, and RST were authors of the second version (2011) of this Cochrane Review.

KR is an author on several other Cochrane cardiac rehabilitation reviews.

RST is an author on several other Cochrane cardiac rehabilitation reviews. RST is currently the co-chief investigator on the programme of research with the overarching aims of developing and evaluating a home-based cardiac rehabilitation intervention for people with heart failure and their carers (UK NIHR PGfAR RP-PG-0611-12004). RST is currently a coinvestigator on the CADENCE study (funded by the UK NIHR HTA 12/189/06). This study is a feasibility and pilot study aimed at developing enhanced psychological care for people with new onset depression using cardiac rehabilitation services (ISRCTN34701576).

## SOURCES OF SUPPORT

### Internal sources

- Department of Social Medicine, University of Bristol, UK.
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- Cardiff University, UK.
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- Supporting Suzanne Richards, Lindsey Anderson, and Rod Taylor
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- Supporting Rod Taylor. The views and opinions expressed therein are those of the review authors and do not necessarily reflect those of National Health Service, the UK NIHR, or the UK Department of Health
- Academic Unit of Primary Care, Leeds Institute of Health Sciences, University of Leeds, UK.
- Supporting Suzanne Richards

### External sources

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- The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR Health Technology Assessment Programme, NIHR, National Health Service, or the Department of Health, UK.
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- Cochrane Infrastructure funding to the Heart Group, UK.
- The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NIHR Systematic Reviews programme, NIHR National Health Service, or UK Department of Health

## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This current (third) update relates to a review first published in 2004 and subsequently updated in 2011. The following changes were implemented to this 2016 update, modifying the procedures reported in 2011.

In terms of eligibility criteria, cardiac rehabilitation services are offering care to more varied populations of people with cardiac conditions (e.g. people with heart failure or arrhythmias). Building on the inclusion criteria proposed by [Whalley 2011](#), this third update now includes trials evaluating psychological interventions recruiting cardiac populations where at least 50% or more of the participant population has an acute coronary syndrome or angina. More recent studies are also seeking to test psychological interventions in comorbid populations (i.e. people with depression, and either acute coronary syndrome *or* diabetes). These studies were deemed eligible for inclusion as long as the outcome data were reported separately and could be extracted for the subgroup of people with heart disease.

Regarding data synthesis, we also report meta-analysis of the outcome of participant-reported stress levels, and the findings from studies reporting participants' levels of return to work, or data on economic evaluations conducted alongside trials. The GRADE assessment of the quality of evidence for each of the primary outcomes is also reported. Finally, we have narrowed the scope of the meta-regression analysis by limiting our investigation to a smaller number of key parameters compared with those explored in the second update.

## NOTES

All stages of this review update were conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011) and complied with all “mandatory” requirements of The Methodological Expectations of Cochrane Intervention Reviews (MECIR) (Chandler 2013). Later stages of the update process also met the more rigorous “highly desirable” MECIR standards, reflecting changes in the enforcement of these standards by the Cochrane Heart Group.

## INDEX TERMS

### Medical Subject Headings (MeSH)

\*Psychotherapy; Anxiety [\*therapy]; Cause of Death; Coronary Disease [mortality; \*psychology]; Depression [\*therapy]; Myocardial Infarction [epidemiology; prevention & control; \*psychology]; Myocardial Revascularization [\*psychology; statistics & numerical data]; Randomized Controlled Trials as Topic; Reoperation; Stress, Psychological [epidemiology]

### MeSH check words

Aged; Female; Humans; Male; Middle Aged